MIDTOWN NUTRITION CARE
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September 11, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: August 22, 2006 Proposed Rule, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Issue Identifier: PROVISIONS—MEDICAL NUTRITION THERAPY SERVICES, CPT 97802-4, G0270-1 (II. Provisions of the Proposed Rule, A. Resource-Based Practice Expenses (PE) RVU Proposals for CY 2007, 3. Medical Nutrition Therapy Services, 71 FR 48987)

Dear Sir or Madam:

Midtown Nutrition Care (Midtown), a single specialty nutrition group practice with 7 registered dietitians, respectfully submits the following comments.

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Summary of Points

The work RVUs for the three individual 15-minute medical nutrition therapy codes CPT 97802, 97803 and G0270 should all be the same. The work RVUs for the medical nutrition therapy codes should be based on the 15-minute consultation code CPT 99241 rather than on the 15-minute and 30-minute physical therapy codes CPT 97110 and 97150.

Inadequate Reimbursement = Lack of Access

1. Last year, in the Calendar Year 2006 Proposed Rule, CMS proposed eliminating the nonphysician work pool, formerly known as the zero-work pool, and stated: "We recognize that there are still some outstanding issues that need further consideration, as well as input from the medical community. For example, although we believe that the elimination of the nonphysician work pool would be, on the whole, a positive step, some practitioner services, such as audiology and medical nutrition therapy, would be significantly impacted by the proposed change.... We, therefore, welcome all comments on these proposed changes..." (70 FR 45777, second column).

2. As members of the medical community Midtown submitted comments dated September 22, 2005 from our group and from the original sponsor of the medical nutrition therapy benefit bills, Congressman Jose Serrano. Comments were also submitted by our professional society, the American Dietetic Association (ADA).

3. These comments showed that even without further reduction current reimbursement rates are inadequate, and urged that appropriate work RVUs be assigned to the Medical Nutrition Therapy codes in order to give effect to the intention of Congress to provide adequate payment for these services, so that access to these services would become generally available to the Medicare beneficiaries entitled thereto, namely, patients with diabetes or renal disease.

4. That the access to care envisioned by Congress does not exist is shown by the following three items. First, prior to passage of the medical nutrition therapy benefit the Congressional Budget Office estimated the annual cost of medical nutrition therapy services to be 60 million dollars, but only a few million dollars have been spent annually since the benefit became available in 2002. Second, this represents visits by only about 250,000 beneficiaries out of an estimated 8 million beneficiaries with diabetes or renal disease. Third, only about 10% of dietitians (7,000 out of 65,000 nationwide) have become Medicare providers, compared with over 90% of physicians. For a discussion of these three items, see Journal of the American Dietetic Association, June 2005, p. 990 and p. 995 (footnote references).

5. In our case, as our September 22, 2005 comment showed, Medicare pays less than half the fees paid by insurers in our area that have independently valued these codes. Medicare's fees are well below our break-even level. Therefore we cannot afford to treat Medicare patients and none of us has become a Medicare provider. We turn away a couple of Medicare patients every day and most of these patients are unable to obtain medical nutrition therapy services because virtually none of the dietitians in our area accept Medicare.

6. In the Calendar Year 2006 Physician Fee Schedule Final Rule no decision was made regarding medical nutrition therapy work RVUs; that decision was put off to this year: "Because we are maintaining the NPWP for 2006, we are deferring our decision regarding work RVUs for audiology, speech language pathology and medical nutrition pending further discussions with the specialties." (70 FR 70134, first column).

7. In the Calendar Year 2007 Proposed Rule CMS stated it would establish work RVUs and remove clinical labor time in the practice expense direct input database: "Because we propose to add the work RVUs to these services, the MNT clinical labor time in the direct input database would be removed with the adoption of this proposal." (71 FR 48987, third column).

8. The assignment of work RVUs coupled with the removal of clinical labor time from the practice expense direct input database would raise the fully implemented non-facility total RVU of the 15-minute new patient visit code CPT 97802 from **0.48** to **0.58**, leave the 15-minute established patient visit codes CPT 97803 and G0270 total RVU of **0.48** unchanged, and raise the 30-minute group codes CPT 97804 and G0271 total RVU from **0.19** to **0.32**. (70 FR 70457, 70462; 71 FR 49231, 49235).

9. Given the approximately 10% adjustment required to preserve budget neutrality (71 FR 37241, first-second columns), this means that the new patient visit code would pay about 5% more than currently, the established patient visit codes would pay about 5% less than currently, and the group codes would pay about 50% more than currently. Although the group fees would be adequate, neither our practice nor the practices or employment settings of other dietitians have many group visits compared to individual visits. Therefore if these RVUs are carried over to the Final Rule our practice and other dietitians will still be unable to afford to treat Medicare patients, allowing the lack of access to care to continue.

The Work RVUs Should Be the Same for the Individual Codes

10. The proposed work RVUs are those recommended on an interim basis by HCPAC in July 2000, transmitted to CMS by memo dated August 1, 2000, a copy of which is attached as Attachment B.

11. These recommendations were based on a RUC survey conducted in March 2000 (Attachment F) for seven proposed, but never adopted, Medical Nutrition Therapy codes, 3 initial visit codes, 3 follow-up visit codes and 1 group visit code, modeled after the office visit code series CPT 99201-99205, 99211-99215.

12. Unlike the time-based codes that were adopted, these 7 codes were based on level-of-complexity. Thus the survey data showed that follow-up visits would have lower RVUs because at the same level of complexity the follow-up visit will take less time than the initial visit.

13. But because a shorter visit will take less time, it will also have fewer 15-minute increments. Therefore there is no need to value the 15-minute follow-up visit increment less than the 15-minute initial visit increment. In fact doing so amounts to a double reduction of the fee, first for fewer 15-minute increments, and then a lower RVU for the each increment.

14. HCPAC stated at the bottom of the first page of the July 2000 Recommendations (Attachment B): "This recommendation maintains the relativity of CPT code 97803 and 97804 as presented by the survey data and original work relative value recommendations from the American Dietetic Association." Somehow HCPAC overlooked the fact that the survey data was based on the never adopted level-of-complexity codes, while the adopted codes were purely time-based codes.

15. Using the survey data, HCPAC valued the15-minute follow-up increment 73% less than the 15-minute initial visit increment, estimating that the typical CPT 97802 visit would take 75 minutes (pre, intra and post visit time), while the typical CPT 97803 visit would take 55 minutes (pre, intra and post visit time), or 73% less time ($55 \div 75 = 73\%$).

16. All of the CPT codes that are time-based, other than the Medical Nutrition Therapy codes, use the same code for their initial and follow-up visits, so their initial and follow-up time increments will pay the same. See, for example, the preventive medicine counseling codes CPT 99401-99412 and the psychiatric therapeutic psychotherapy codes CPT 90804-90829.

17. In fact, were it not for CMS's need to use CPT 97803 and G0270 to keep track of the number of follow-up visits and change-of-diagnosis follow-up visits, it would need only one code for all individual visits. But just because CMS needs to use two additional follow-up visit codes is no reason to value the 15-minute increments of those codes less than the 15-minute increment of the initial visit code.

18. CMS recognized that initial and follow-up time-based medical nutrition therapy codes should be valued the same when CMS valued the later-created group change-of-diagnosis 30-minute follow-up code G0271 the same as the CPT 30-minute group code CPT 97804. (70 FR 70457, 70462).

19. But more to the point, the question of whether the individual 15-minute codes would be valued the same or differently was an issue once before, in the preparation of the Calendar Year 2002 Physician Fee Schedule. The Calendar Year 2002 Proposed Rule had proposed a lesser value for the 15-minute follow-up increments. The issue was fully discussed in the Proposed Rule, in comments thereto, and in the Final Rule, which concluded that all of the time-based Medical Nutrition Therapy codes should have the same hourly rate: "A commenter representing dietitians asked us to review the relativity of payment across the three medical nutrition CPT codes. The commenter indicated that payment for CPT code 97803 was set at 72.9 percent of proposed RVUs for CPT 97802 and 97804 was set at 31 percent of CPT code 97802. The commenter argues that, because reassessments are shorter than initial assessments, the proposed RVUs are actually discounted twice (that is, less payment per 15 minutes of time as well as less total time). They believe the value of CPT codes 97802 and 97803 should be identical.... We have reviewed the payments for CPT codes 97802 and 97803 and agree with the commenter that these two codes should have the same values. The essential difference between an initial and follow up medical nutrition therapy service is the time spent performing the service. Initial visits will be longer than follow-up visits and will likely involve Medicare payment for more increments of service. We will pay less for follow up visits because they will typically involve fewer 15-minute increments of time than an initial visit. The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the proposed rate for CPT code 97802. We have also changed the payment rate for CPT code 97804 assuming that the code will normally be billed for 4 to 6 patients with the average of 5. Using the revised values, the payment rate for group medical nutrition therapy would approximate the hourly rate paid for other medical nutrition therapy services." (68 FR 55280, first-second columns).

20. That reasoning was sound and remains sound and should continue to be followed, rather than create a **0.08** less work RVU for CPT code 97803 and G0270 (0.45 – 0.37 = 0.08). (71 FR 49231, 49235).

Use the Work RVU of the 15-Mintue Consultation Code

21. CMS may accept or reject HCPAC work RVU recommendations. (71 FR 37173, third column). In this instance we submit that CMS should reject the July 2000 HCPAC interim recommendations, which base the medical nutrition therapy work RVUs on the 15-minute and 30-minute physical therapy codes CPT 97110 and 97150, and instead base the work RVUs on the 15-mnute consultation code CPT 99241.

22. The July 2000 HCPAC interim recommendations regarding the new Medical Nutrition Therapy codes were unusual in that they were initially submitted for the Calendar Year 2001 Physician Fee Schedule before CMS had the statutory authority to

value these codes for Medicare payment (71 FR 48987, first-second columns), because the law that created the medical nutrition therapy benefit was not enacted until later, in December 2000, and created the benefit for these services starting in the Calendar Year 2002. See PL 106-544, Appendix F, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Section 105, Coverage of Medical Nutrition Therapy Services for Beneficiaries With Diabetes or a Renal Disease, and the published legislative history set forth in the Statement of the Manager For Section 105, both attached as Attachment E.

23. When HCPAC was making its interim work recommendations, HCPAC did not know what the statute would eventually contain. Therefore HCPAC looked solely to the text of the Medical Nutrition Therapy codes CPT 97802-4 which describe medical nutrition therapy services in bare-bones terms as "assessment [or re-assessment] and intervention, individual [or group], face-to-face with the patient, each 15 [or 30] minutes." On the other hand the statute defines medical nutrition therapy services much more comprehensively as "diagnostic, therapy and counseling services for the purpose of disease management", Section 105(b) of BIPA, 42 U.S.C. 1395x(vv)(1), and provides that payment of 85% to dietitians be determined "for the same services if furnished by a physician." Section 105(c)(2) of BIPA, 42 U.S.C. 1395l(a)(1)(T).

24. Since HCPAC was recommending work RVUs when it was not even cognizant of what the statutory definition would be, HCPAC was able to compare the15- and 30-minute individual and group medical nutrition therapy codes to "other modality or treatment codes" (middle of the first page of the July 2000 Recommendations, Attachment B), in this case the 15- and 30-minute individual and group physical therapy codes CPT 97110 and 97150.

25. These treatment codes are poor comparisons given the (now known) statutory definition of medical nutrition therapy in Section 105(b), 42 U.S.C. 1395x(vv)(1), which includes diagnosis and counseling as well as therapy.

26. In the 2002 Physician Fee Schedule Proposed and Final Rules CMS had compared medical nutrition therapy services to the 15-minute preventive medicine counseling code CPT 99401: "Commenters...believe that medical nutrition therapy payment should not be based on comparison to a preventive medicine code (CPT code 99401) in the zero-work pool methodology. The commenters indicated that preventive medicine services omit the problem-oriented components of the comprehensive history, as well as other essential assessment points, such as the patient's chief complaint and history of present illness." (66 FR 55279, third column-55280, first column).

27. In prior submissions to CMS Midtown had also proposed that the work RVUs for the Medical Nutrition Therapy codes could be based on the 15-minute preventive medicine counseling code CPT 99401. However Section 105(b), 42 U.S.C. 1395x(vv)(1), defines medical nutrition therapy services as services provided "for the purpose of disease management", that is, for patients with established illness. So a crosswalk to CPT 99401 would not be appropriate, because the CPT text prior to Sections 99401-99429 states (third paragraph of text): "These codes [preventive medicine counseling codes] are not to

be used to report counseling and risk factor reduction interventions provided to patients with symptoms or established illness. For counseling individual patients with symptoms or established illness, use the appropriate office, hospital or consultation or other evaluation and management codes [emphasis supplied]."

28. A more appropriate crosswalk, according to the text quoted above, would be to the work RVU of an office visit or consultation code.

29. Section 105(b), 42 U.S.C. 1395x(vv)(1), provides that a medical nutrition therapy visit be "pursuant to a referral by a physician", to whom a report is sent post-visit. Therefore the visit could be considered a consultation. If so, the work RVU could be that of the 15-minute consultation code CPT 99241, which has a work RVU of **0.64** as of the 2006 Physician Fee Schedule, and the same **0.64** is proposed for the 2007 Physician Fee Schedule. (71 FR 37218, second-third columns; 71 FR 49232).

30. The medical nutrition therapy visit could also be considered an office visit. If so, the work RVU could be that of the 15-minute established patient office visit code CPT 99213, which has a work RVU of **0.67** as of the 2006 Physician Fee Schedule (70 FR 70458) and a proposed work RVU of **0.92** for the 2007 Physician Fee Schedule. (71 FR 37218, second-third columns; 71 FR 49232).

31. CMS could use either the work RVU of CPT 99241 or the work RVU of CPT 99213 as the work RVU for the 15-minute individual Medical Nutrition Therapy codes CPT 97802, 97803 and G0270; and as the basis for the work RVU for the 30-minute group codes CPT 97804 and G0271 in the same manner as was done in the Calendar Year 2002 Physician Fee Schedule Final Rule; that is, by multiplying the CPT 97802 RVU by 2 then dividing by 5. (66 FR 55281, first column).

32. The Calendar Year 2002 Physician Fee Schedule Final Rule, however, had rejected a valuation crosswalk to E/M codes, making the following analysis for the first time in the Final Rule, though not in the Proposed Rule (so no comments may have been received questioning such analysis): "We do not believe that it is appropriate to compare medical nutrition therapy provided by a registered dietitian to an E/M service provided by a physician. Registered dietitians do not take medical histories, they are not trained and do not perform physical examinations, nor do they make medical decisions. Furthermore, when physicians use an E/M code, they typically have also performed a medical history, physical examination, and engaged in medical decision making as part of that service. If such an individual performed a service that met the requirements of an E/M service, then it would be appropriate for him or her to report an E/M service [emphasis supplied]." (66 FR 55278, third column).

33. This analysis misread the statute, which specifies that the amount paid be determined by comparing medical nutrition therapy services provided by a physician, not by comparing medical nutrition therapy services provided by a registered dietitian. Section 105(c)(2), 42 U.S.C. 1395l(a)(1)(T), states "the amount paid shall be...85 percent of the amount determined ... for the same services if furnished [i.e., provided] by a physician".

(See the third sentence of the Statement of the Manager For Section 105, Attachment E, "... if such services were provided by a physician [emphasis supplied].")

34. CMS has acknowledged that: "Physicians will occasionally meet the statutory qualifications to be considered a registered dietitian or nutrition professional who can bill Medicare for medical nutrition therapy services. (66 FR 55279, second column).

35. If a physician who is also a dietitian has a medical nutrition therapy visit "for the purpose of disease management" the physician will perform the 3 key components, taking a medical history, performing a physical examination and engaging in medical decision making, as part of the service. In fact, the text following CPT 97802-4 states: "For medical nutrition therapy assessment and/or intervention performed by a physician, see Evaluation and Management or Preventive Medicine service codes." (As noted above, since the Section 105(b), 42 U.S.C. 1395x(vv)(1), requires Medicare-covered visits to be for patients with established illness, only the office visit/consultation codes, not the preventive medicine codes, could be used for a Medicare-covered visit.)

36. To qualify for CPT 99241 or CPT 99213 these 3 components do not need to be at high levels. CPT 99241 is a level one E/M code that has the following, a problem focused history, a problem focused examination, and straightforward medical decision making; CPT 99213 is a level three E/M code that has the following, an expanded problem focused history, an expanded problem focused examination, and medical decision making of low complexity. (71 FR 37211, 37214).

37. Similarly, a registered dietitian who is not a physician will take a problem focused or expanded problem focused medical history, reviewing labs and other reports from the referring physician and interviewing the patient; will perform a limited medical examination, which will include anthropometric measurements, and could also include additional examination such as taking blood pressure or blood glucose, or examining affected body areas such as the skin for diabetic acanthosis nigricans, or for pressure ulcers that may be connected with protein-calorie malnutrition; and engage in straightforward or low complexity medical decision making, which will include prescribing or modifying nutrient and/or micronutrient intake, administration or supplementation, and could include additional medical decision making such as modifying insulin doses to match carbohydrate intake using carbohydrate counting/insulin ratios.

38. Because the levels of the history taking, physical examination and decision making in the visit (whether by a physician who is also a dietitian, or by a dietitian who is not a physician) are often low, the lower levels of medical history, physical examination and decision making contained in the 15-minute consultation code CPT 99241 make the work RVU of that code (current and proposed work RVU of **0.64**) more appropriate than the work RVU of CPT 99213, which has higher levels of history taking, physical examination and decision making (current work RVU of **0.67**, proposed work RVU of **0.92**). Therefore we recommend using the work RVU of CPT 99241.

39. It is also appropriate to use the work RVU of CPT 99241 because time may be the determining factor in assigning the level of the service. When time is the determining factor, the work RVU of CPT 99241 generates the lowest (and therefore most modest) work RVUs for visits lasting 15 minutes, 30 minutes or one hour.

40. The Evaluation and Management Service Guidelines state, under the heading "Levels of E/M Services": "The descriptors for the levels of E/M services recognize seven components, six of which are used in defining the levels of E/M services. These components are: History, Examination, Medical decision making, Counseling, Coordination of care, Nature of presenting problem, Time. The first three of these components (history, examination, and medical decision making) are considered the key components in selecting a level of E/M services."

41. However the Evaluation and Management Service Guidelines state later, under the heading "Select the Appropriate Level of E/M Services Based on the Following", "3. When counseling and/or coordination of care dominates (more than 50%) the physician/patient and/or family encounter (face-to-face time in the office or other outpatient setting or floor/unit time in the hospital or nursing facility), then time may be considered the key or controlling factor to qualify for a particular level of E/M services."

42. Although the definition of medical nutrition therapy services, Section 105(b), 42 U.S.C 1395x(vv)(1), includes three services, "diagnostic, therapy, and counseling services", counseling services will almost always dominate (more than 50%) the encounter. Therefore, time may be considered the key or controlling factor.

43. The following chart compares CPT 99241 to all other office visit/consultation codes that are 15 minutes or divisible by 15 minutes (all other codes are either less than 15 minutes or not divisible by 15 minutes). The chart shows that for both the current and proposed RVUs, the work RVU of CPT 99241 generates the lowest (most modest) work RVUs for visits lasting 15 minutes, 30 minutes or one hour. (70 FR 70458; 71 FR 37218, second-third columns; 71 FR 49232):

CPT Code	15-Minute RVU	30-Minute RVU	One-Hour RVU
99241	**0.64** Current	**1.28** (2 increments)	**2.56** (4 increments)
	0.64 Proposed	**1.28** (2 increments)	**2.56** (4 increments)
99213	**0.67** Current		
	0.92 Proposed		
99242		**1.29** Current	
		1.34 Proposed	
99203		**1.34** Current	
		1.34 Proposed	
99244			**2.58** Current
			3.02 Proposed
99205			**2.67** Current
			3.00 Proposed

The ADA Prefers Using an E/M Code RVU

44. All of the registered dietitians at Midtown are members of our professional society, the American Dietetic Association, and we have observed over the past 6 years that the ADA has consistently communicated its preference for work values based on E/M codes, in particular the level three, 15-minute and 30-minute, office visit codes CPT 99213 and 99203. As CMS observed, "the ADA compared work associated with their services to physician E/M services of CPT 99203 and 99213, which have respective work values of **1.34** and **0.67**." (71 FR 48987, second column).

45. Because CMS stated in the Calendar Year 2006 Final Rule that it was "deferring our decision regarding work RVUs for audiology, speech language pathology and medical nutrition pending further discussion with the specialties", ADA submitted a January 3, 2006 letter (Attachment C). In the letter ADA stated, at page 3, "there is external support for a far more transparent approach to MNT RVUs. AMA indicates in the CPT 2005 publication, 'for medical nutrition therapy assessments and/or intervention performed by a physician, see Evaluation and Management or Preventive Medicine service codes.' If CMS believes the MNT statute for payment must be followed, then the agency should base the RD payment rate on 85% of the total physician RVUs for these codes (eg. E&M code 99203)." Nowhere in that letter are the HCPAC interim recommendations even mentioned.

46. In its March 24, 2006 follow-up letter to CMS (Attachment D), ADA again states its preference for E/M work values (bottom of page 1-top of page 2): "The most straightforward way to correct this anomaly is to establish work values for codes 97802, 97803 and 97804. CMS could crosswalk the work RVU from either the Evaluation and Management codes, or Preventive Medicine codes; the codes physicians are directed to use when they provide MNT services.... Alternatively, CMS could use the HCPAC interim work RVUs for the MNT codes. These values could be used but only with caution since they were not valued as physician services and therefore reflect a discounted service [emphasis supplied]."

47. CMS stated in the Calendar Year 2007 Proposed Rule: "More recently, the ADA requested us to reconsider our decision not to accept the HCPAC recommended work RVUs [emphasis supplied]." (71 FR 48987, second column). A more accurate statement would be: "More recently, the ADA requested us to reconsider our decision not to accept work RVUs."

48. When ADA wrote its March 24, 2006 letter it was not clear whether CMS would establish work values, so in an effort to make CMS comfortable with the concept ADA demonstrated to CMS that there were several sources upon which to base work values. ADA listed four such sources in the following order, first ADA's preference, an E/M code, then a preventive medicine code, then the 2000 RUC survey data, then the HCPAC interim recommended RVUs, if CMS "would adjust the HCPAC work professional services upward to recapture the value of the remaining 15%".

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Congress of the United States
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Washington, DC 20515–3216

September 11, 2006

COMMITTEE:
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Dr. Mark B. McClellan
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
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Dear Dr. McClellan:

I was the sponsor of the original medical nutrition therapy benefit bills in the mid-90's and cosponsor of the 1999 bill that eventually became the law, as Section 105 of PL 106-544, entitled "Coverage of Medical Nutrition Therapy Services for Beneficiaries with Diabetes or Renal Disease."

As you review the rule pertaining to medical nutrition therapy benefits, please be aware of Congress' intent that payment be sufficient to provide access to care for the beneficiaries of the service. Establishing an appropriate work value for nutrition therapy based upon "the same services if furnished by a physician" would promote access to these services and thus comply with the intent of the law. Therefore I ask that you perform a prompt, thorough, reasoned analysis of the appropriateness of the work values to be assigned so that better access to care may be made available as soon as possible.

I have reviewed the comments of Midtown Nutrition Care and would ask that they be given every consideration as the rule in question is reviewed.

Sincerely,

Jose E. Serrano
Member of Congress

Attachment A page 1 of 1

Memo to: Paul Rudolf, MD, JD

From: Don E Williamson, OD, Co-Chair, HCPAC

Date: August 1,2000

Subject: HCPAC Review Board Recommendations for Medicare Fee Schedule 2001

It is with pleasure that I submit to the Health Care Financing Administration (HCFA), on behalf of the RUC Health Care Professional Advisory Committee (HCPAC) Review Board, work relative value and direct practice expense inputs for new and revised codes for CPT 2001. This year, the HCPAC will be submitting two sets of recommendations, the first represent recommendations for Sensory Integrative Technique Procedures and the second, Medical Nutrition Therapy. At this time, we are forwarding interim recommendations for the Medical Nutrition Therapy procedures as the American Dietetic Association may choose to bring additional data forward to the HCPAC.

We appreciate the Health Care Financing Administration (HCFA)'s representatives' participation in the HCPAC process.

Should you have any questions regarding the material contained herein, please contact Sherry Smith at (312) 464-4308 or Dawn K. Gonzalez at (312) 464-4308.

cc: Rick Ensor
Carolyn Mullen
Terry Kay

RUC HEALTH CARE PROFESSIONALS ADVISORY COMMITTEE REVIEW BOARD
SUMMARY OF RECOMMENDATIONS

July 2000
Medical Nutrition Therapy

CPT Code 97802

Work Relative Value Recommendation
New code 97802 *Medical nutrition therapy; initial assessment and intervention, individual, face-to-face- with the patient, each 15 minutes* was created to describe both the assessment as well as intervention which regularly includes behavior components requiring advanced skills and knowledge by a registered dietician. In addition, these patients are usually very sick and complex due to the shift of patients receiving treatment from the inpatient to the outpatient setting. This new code combines Medical Nutrition Therapy assessment/evaluation and intervention/treatment, and both of these services are included in the Medical Nutrition Therapy provided to the patient during the first visit. The 15 minute time value is similar to many other modality or treatment codes. For example, the pre- intra- and post-service times of 97802 (3 minutes, 15 minutes, 5 minutes) are comparable to CPT code 97110 *Therapeutic procedure, one or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility* (5 minutes, 20 minutes, 5 minutes) work RVW of .45. Another comparable CPT code is 97001 *Physical therapy evaluation* (pre-5 minute, intra- 30 minutes, and post-service –15 minutes)(work RVW-1.20) which is not a timed procedure but usually represents 30-45 minutes of work. This new MNT code usually is reported in four increments (50 minutes spent fact-to-face with patient or a total time (pre, intra and post) of 75 minutes) for the medical nutrition therapy assessment/evaluation and patient intervention and self-management training. **Based on these reference procedures, the Review Board agreed to an interim work relative value of .45 for CPT Code 97802.** The American Dietetic Association may gather additional data and develop further proposals with the CPT Editorial Panel.

Practice Expense Recommendation
The HCPAC agrees to the attached list of practice expenses for CPT Code 97802.

CPT Code 97803

Work Relative Value Recommendation
The HCPAC Review Board agreed that the new code 97803 *reassessment and intervention, individual, face-to-face- with the patient, per 15* should be valued at .37 work relative value units. This recommendation maintains the relativity of CPT code 97803 and 97804 as presented by the survey data and original work relative value recommendations from the American Dietetic Association. This new code usually is reported in two to three increments (30 minutes face-to-face time with the patient or a total time (pre, intra and post) of 55 minutes) for the patient reassessment

and intervention. **Therefore, the Review Board recommends an interim work relative value of .37 for CPT 97803**. The American Dietetic Association may gather additional data and develop future proposals with the CPT Editorial Panel.

Practice Expense Recommendation
The HCPAC agreed that the attached list of practice expenses represent the resources necessary to perform the procedure in a non-facility setting.

CPT Code 97804

Work Relative Value Recommendation
The new code 97804 *Medical Nutrition therapy group (2 or more individuals), per 30 minutes* was compared to CPT Code *97150 Therapeutic procedures(s), group (2 or more individuals)* work RVW =.27. This new code usually is reported in two increments (60 minutes face-to-face time or a total (pre, intra, and post-time of 90 minutes for a group or a hour for a group setting of 4-6 while CPT Code 97150 is usually reported in three increments (45 minutes) for a group setting of 5 individuals. **Based on this comparison, the HCPAC Review Board agreed that this new code 97804 should be valued at an interim work RVW of .25.** The American Dietetic Association may gather additional data and develop further proposals with the CPT Editorial Panel.

Practice Expense Recommendation
The HCPAC agreed that the attached list of in office direct inputs represent the practice cost to perform this procedure.

Attachment B - page 3 of 4

Attachment B - page 4 of 4

CPT Code (●New) (▲Revised) (D Deleted) (E Editorial)	CPT Descriptor	Global Period	Work RVU Recommendation
●97802	Medical nutrition therapy; initial assessment and intervention, individual, face-to-face- with the patient, each 15 minutes	XXX	0.45 (Interim)
●97803	reassessment and intervention, individual, face-to-face- with the patient, per 15 minutes	XXX	0.37 (Interim)
●97804	group (2 or more individuals(s)), each 30 minutes (For medical nutrition therapy assessment and/or intervention performed by a physician, see **Evaluation and Management** or **Preventive Medicine** service codes)	XXX	0.25 (Interim)

*The HCPAC Review Board agreed that these three Medical Nutrition Therapy Codes should be valued at interim work RVWs while the American Dietetic Association gathers additional data and considers code restructure for discussion at the HCPAC and/or the CPT Editorial Panel's upcoming meeting(s).

American Dietetic Association
Your link to nutrition and health.[sm]

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Policy Initiatives and Advocacy
1120 Connecticut Avenue, Suite 480
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January 3, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
7500 Security Lane
Baltimore, MD 21244-8017

RE: 42 CFR Parts 405, 410, 411, 413, 414, 424, 426 [CMS-1502-FC].
Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006.

Dear Dr. McClellan:

The American Dietetic Association (ADA) appreciates this opportunity to re-affirm our comments on the Notice of Final Rule for the CY 2006 Physician Payment Schedule published November 21, 2005 (70 FR 70116). We urge you to consider this information as you refine the Final Rule for CY 2006 and initiate procedures to revise methodology for relative values for the following year's rule.

The ADA represents nearly 65,000 food and nutrition professionals working to improve the nutritional status of Americans. As primary prevention, strong evidence indicates that nutrition helps promote health and functionality and affects each individual's quality of life. As secondary and tertiary prevention, medical nutrition therapy (MNT) is a cost-effective disease management strategy that lessens chronic disease risk, and which slows disease progression and reduces symptoms. Medicare Part B covers MNT provided by registered dietitians (RDs) for diabetes and chronic renal disease.

Telehealth for Individual MNT

ADA supports the final rule decisions to add individual MNT to the Medicare list of services that can be provided via telehealth, and recognize registered dietitians (RDs) and nutrition professionals as qualified healthcare professionals who can submit claims for individual MNT provided via telehealth. ADA welcomes the opportunity to assist CMS in educating Medicare RD providers on telehealth services and to inform and encourage physician practitioners and beneficiaries of this new service delivery option.

PE Methodology and Elimination of the Non-Physician Work Pool

ADA agrees with CMS' decision to withdraw the entire PE methodology proposal and to refine the process for the CY 2007 proposed rule.

We ask to participate in the process as a full partner when CMS considers how to revise the methodology to calculate CPT code relative values. When CMS convenes a meeting with interested medical societies to discuss the direct and indirect PE methodology and elimination of the non-physician work pool, as well as meet individually with groups to discuss their particular concerns, ADA representatives need to cover our unique experience and knowledge along with the other interested medical societies. We also request to meet separately with CMS to discuss the medical nutrition therapy CPT code RVUs, including the direct and indirect PE inputs for the codes.

The current methodology and the proposed bottom-up methodology for MNT services fail to appropriately recognize RD work. With the proposed CY 2006 RVUs for MNT CPT codes, the agency once again has overlooked the intent of Congress regarding the implementation (and payment) for medical nutrition therapy services. In particular:

- *MNT code PE inputs are not valid.*
  RD work should be fully recognized and accounted for in the code RVUs.
  The current direct inputs do not accurately reflect the RD's full clinical labor and professional service that is required to provide MNT. The inputs fail to represent the RD's pre-, intra-, and post-work times to provide this service as the current values significantly underestimate, or omit certain pre- and post-service activities.

  ADA recommends PE time be allocated consistently within the three MNT codes for pre-services, such as reviewing medical records and laboratory data, equipment set-up, and other clinical activities (greeting the patient, treatment room set-up); and for post-services such as dismantling and storing equipment and educational materials such as food models; documentation and conducting follow-up communications with the referring physicians, patients and family members as appropriate and necessary. CMS has not accurately represented these activities in the direct input data used to calculate the MNT RVUs.

  PE data that ADA discussed with the AMA PEAC in February 2005 indicates that the following minutes of clinical labor are accurate:

  - 39 minutes total clinical labor time, including RD professional work for 97802 and 97803 per unit code;
  - 28 minutes total clinical labor time, including RD professional work for 97804 per unit code.

  These work data are significantly different from the arbitrary direct input values that CMS has used in the proposed PE calculation of RVU for the MNT codes -- 25 minutes 97802; 22 minutes for 97803, and 9 minutes for 97804. (See accompanying table).

- *The RVUs for initial MNT (97802) and follow-up MNT (97803) should be the same.*
  Since the MNT codes are time-based, the complexity and amount of time spent completing the pre-, intra-, and post-service times will be reflected in the number of

units used for each code. Therefore, the four-minute difference that the agency currently used in the direct PE values for determining the total RVUs is not appropriate. Both initial and follow-up MNT for individual encounters should have the same direct PE RVUs.

- *CMS should pay RDs and qualified nutrition professionals 100% of the MNT code RVUs or pay 85 percent of designated physician codes.*
  While current policy is inconsistent with the authorizing statute, it also lacks intellectual integrity. In the agency's determination that there is no physician work for MNT services, and its policy to take 85 percent of the physician fee schedule values for the MNT CPT codes, the agency has created an unfair payment anomaly towards registered dietitians and nutrition professionals who provide and bill for the services using the MNT CPT codes. If the agency continues to support the premise that there is no physician work for the MNT codes, this 'double discount' can be corrected by paying RDs 100% of the physician fee schedule.

  Alternatively, there is external support for a far more transparent approach to MNT RVUs. AMA indicates in the CPT 2005 publication, "for medical nutrition therapy assessments and/or intervention performed by a physician, see Evaluation and Management or Preventive Medicine service codes." If CMS believes the MNT statute for payment must be followed, then the agency should base the RD payment rate on 85% of the total physician RVUs for these codes (eg. E&M code 99203). CMS has established a precedent of paying a percentage of the physician fee schedule for codes used by other non-physician practitioners. For example, social workers, certified nurse midwives, physician assistants, and certified nurse specialists are paid a percentage of the physician's fee schedule when providing services that otherwise would have been performed by the physician. The payment amount is based on the physician code to provide the service, not other non-physician practitioner codes for the service.

- *CMS should establish work RVUs for MNT codes provided by RDs.*
  ADA asks the agency to work with our professional association to determine appropriate values and methodology that accurately reflects the professional work of RDs for MNT services.

  If a work RVU cannot be established, ADA asks CMS to consider establishing a new PE category that specifically references the professional's work effort. This would be a separate calculation to the current PE that accounts for clinical labor to support the RD in providing MNT services.

Physician Liability Insurance (PLI) Calculation for RDs

ADA agrees with CMS and the PLI workgroup's decision that nonphysician professionals, such as RDs, incur PLI costs similar to the lowest cost physician specialty; the lowest current risk factor of 1.0. While ADA realizes that CMS was unable to identify all Medicare providers in the proposed and final rule, we note that reference to liability insurance for registered dietitians continues to be omitted in the agencies' comments.

Recognition of RD Medicare Providers by CMS

In closing, in future Federal Register notices and general communications that relate to Medicare Part B providers, ADA urges the agency to include registered dietitians in the printed list of Medicare Part B providers. RDs were omitted in all tables included in CMS-1502-P and CMS-1502-FC, in the list of providers eligible to "opt-out" of Medicare, and other references to

Medicare Part B providers in the proposed rules for the CY 2006 physician fee schedule (70 FR 45764).

ADA looks forward to partnering with CMS in the development of the RVUs for CY 2007 final rule and education on new changes for the 2006 calendar year. Please do not hesitate to call Mary Hager, PhD, RD, Senior Manager, Regulatory Affairs, (202) 775-8277, ext. 1007 or Pam Michael, Director of Nutrition Services Coverage Team, 312-899-4747, with any questions or requests for additional information.

Best regards,

Pam Michael, MBA, RD
Director of Quality, Outcomes and Coverage

Mary H. Hager, PhD, RD
Senior Manager, Regulatory Affairs

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March 24, 2006

Terry Kay
Deputy Director, Hospital and Ambulatory Policy Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard, C4-01-15
Baltimore, Maryland 21244

As a follow up to the CMS February 15th Practice Expense Town Hall meeting, the American Dietetic Association (ADA) submits the following comments to questions addressed by the agency.

In multiple written and verbal communications ADA has asserted that CMS incorrectly valued the medical nutrition therapy (MNT) codes and ignored Congress' intent in establishing fair and equitable policies for the covered MNT services provided by registered dietitians (RDs). As a result of the agencies' current non-physician work pool methodology and the discount applied to the MNT codes, the services are not only undervalued but will be unfairly penalized with even larger reductions using any of the new bottom-up methodologies that have been suggested.

While ADA agrees strongly with CMS' intent to eliminate the non-physician work pool, any bottom up methodology which significantly and unjustly reduces the MNT code RVUs will result in severe provider shortages from RD Medicare providers who will have no choice but to leave Medicare.

The adoption of a new practice expense methodology is an opportunity for CMS to acknowledge and correct the payment inequities previously applied to the MNT codes. We believe a solution should be applied that will allow any methodology selected by CMS to fairly value MNT codes. The obvious solution is one that recognizes the need to use professional work to allocate practice expense.

Recognition of Work
CMS has acknowledged the problems with policies used in valuing the MNT codes. The fair way to correct previous inequities is adopt professional work values for MNT services.

ADA believes the agency has undervalued the MNT CPT codes by refusing to recognize and properly account for the professional work of registered dietitians who perform MNT services. This work is currently imbedded in the PE RVU and as such is valued based solely on time rather than Relative Value which considers time, intensity, training and other factors.

The most straightforward way to correct this anomaly is to establish work values for codes 97802, 97803 and 97804. CMS could crosswalk the work RVU from either the Evaluation and Management codes, or Preventive Services codes; the codes physicians are directed to use when

they provide MNT services. ADA also submitted survey data that identified work RVUs for the three MNT codes (see Appendix 1).

Alternatively, CMS could use the HCPAC interim work RVUs for the MNT codes. These values could be used but only with caution since they were not valued as physician services and therefore reflect a discounted service. When the HCPAC valued the codes, they acknowledged the work as the professional services of the RD. If CMS uses these work values, the agency should increase the values since currently they represent 85% of physician work as RD professional services, not physician work. The agency should adjust the HCPAC work recommendation upward to recapture the value of the remaining 15%, so as to reflect the equivalent level of physician work. Then for actual payment to the RD, this work value could be adjusted to 85% of the physician rate by Medicare payment contractors processing the claims.

ADA realizes that creation of a work RVU for the MNT codes will impact the PE RVUs. While the professional service component from the current PE RVU will be removed, the revised PE direct costs must still include labor time for support services, supplies and equipment. ADA previously submitted PE data to the AMA PEAC at their April 2005 meeting to gather preliminary feedback on revised PE data for the MNT codes. ADA will provide this revised data to you to assist in the re-alignment of the MNT work and PE values.

Proxy Work for direct and indirect PE allocation is an alternative methodology option
While ADA believes establishing a work RVU is the most sound and fair solution for determining RVUs for the MNT codes, if CMS denies this change, an alternative is to establish a proxy work value to determine the direct and indirect PE RVUs for the MNT codes.

In this case, CMS can use the professional work RVUs as described above. Alternatively, CMS could use the time component of professional service multiplied by an appropriate intra-service work per unit of time (IWPUT) value. This methodology would be relevant for codes previously included in the NPWP where the service includes a defined professional component, such as MNT and audiology services. The professional time and IWPUT methodology would not apply to NPWP codes where a procedure has work values associated for interpretation but has zero work by virtue of being a technical component only.

Direct cost utilization rate, particularly for high cost equipment
ADA recommends the agency consider different utilization rates for high end equipment beyond the current 50%; perhaps considering methodology that allows quartile use of equipment, eg. 25%, 50%, 75%, 100% utilization rates. Additionally, ADA requests the agency reconsider the generic 50% utilization rate that is applied to equipment used for MNT services. In some cases, the equipment/supplies are used by RDs throughout the whole patient encounter.

Transition of new methodology
Because the new methodology will negatively impact many codes, ADA recommends CMS transition the changes over several years. Additionally, because the MNT codes may be significantly impacted, such that providers may exit Medicare and leave beneficiaries in a critical state unable to access MNT services, we recommend that CMS implement limits to the potential practice expense payment changes.

Supplemental Surveys
ADA would like to conduct a survey to gather PE data specific to MNT services provided by RDs since there are no data pools available to CMS at this time. Yet the agency has indicated it does not plan to accept any new supplemental survey data.

ADA strongly believes a new survey process is necessary in order to verify data used in CMS calculations, to replace older SMS survey data, and make data available where it is currently missing. By allowing all groups -- physician and non-physician societies -- to gather PE data in a systematic, consistent approach, CMS can create a data base that more accurately represents current PE for the various healthcare groups. This new survey data would also replace the faulty non-physician work pool or CMS' current crosswalks to inappropriate codes. ADA supports this initiative and would participate in future discussions with AMA and CMS on future SMS type surveys.

Conclusions
While ADA recognizes that many medical societies have suggested that the AMA RUC discuss methodology and specific allocation methods at the April 26-30, 2006 RUC meeting, it is imperative that any discussions include alternatives for the NPWP.

To avoid the disastrous impact of the proposed PE methodology to the 2007 physician fee schedule, CMS should recognize professional work for the MNT codes. This is a fair and equitable solution that will offset previous payment inconsistencies for the MNT codes.

ADA requests additional face-to-face meetings with the agency to further discuss our recommended methodologies that will impact future fee schedules. We will contact you to arrange a meeting at your offices.

Regards,

Pam Michael, MBA, RD
Director of Nutrition Services Coverage
312-899-4747

Mary H. Hager, PhD, RD
Senior Manager, Regulatory Affairs
202-775-8277

Statement of the Manager For Section 105

Section 105. Coverage of Medical Nutrition Therapy Services for Beneficiaries With Diabetes or a Renal Disease

The provision would establish, effective January 1, 2002, Medicare coverage for medical nutrition therapy services for beneficiaries who have diabetes or a renal disease. Medical nutrition therapy services would be defined as nutritional diagnostic, therapy and counseling services for the purpose of disease management which are furnished by a registered dietician or nutrition professional, pursuant to a referral by a physician. The provision would specify that the amount paid for medical nutrition therapy services would equal the lesser of the actual charge for the service or 85% of the amount that would be paid under the physician fee schedule if such services were provided by a physician. Assignment would be required for all claims. The Secretary would be required to submit a report to Congress that contains an evaluation of the effectiveness of services furnished under this provision.

****

§105. COVERAGE OF MEDICAL NUTRITION THERAPY SERVICES FOR BENEFICIARIES WITH DIABETES OR A RENAL DISEASE.

(a) Coverage.--Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)), as amended by section 102(a), is amended--

(1) in subparagraph (T), by striking "and" at the end;

(2) in subparagraph (U), by inserting "and" at the end; and

(3) by adding at the end the following new subparagraph:

"(V) medical nutrition therapy services (as defined in subsection (vv)(1)) in the case of a beneficiary with diabetes or a renal disease who--

"(i) has not received diabetes outpatient self-management training services within a time period determined by the Secretary;

"(ii) is not receiving maintenance dialysis for which payment is made under section 1881; and

"(iii) meets such other criteria determined by the Secretary after consideration of protocols established by dietitian or nutrition professional organizations;".

(b) Services Described.--Section 1861 (42 U.S.C. 1395x), as amended by section 102(b), is amended by adding at the end the following:

"Medical Nutrition Therapy Services; Registered Dietitian or Nutrition Professional

"(vv)(1) The term 'medical nutrition therapy services' means nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional (as defined in paragraph (2)) pursuant to a referral by a physician (as defined in subsection (r)(1)).

"(2) Subject to paragraph (3), the term 'registered dietitian or nutrition professional' means an individual who--

"(A) holds a baccalaureate or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics, as accredited by an appropriate national accreditation organization recognized by the Secretary for this purpose;

"(B) has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and

"(C)(i) is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed; or

"(ii) in the case of an individual in a State that does not provide for such licensure or certification, meets such other criteria as the Secretary establishes.

"(3) Subparagraphs (A) and (B) of paragraph (2) shall not apply in the case of an individual who, as of the date of the enactment of this subsection, is licensed or certified as a dietitian or nutrition professional by the State in which medical nutrition therapy services are performed.".

(c) Payment.--Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)) is amended--

(1) by striking "and" before "(S)"; and

(2) by inserting before the semicolon at the end the following: ", and (T) with respect to medical nutrition therapy services (as defined in section 1861(vv)), the amount paid shall be 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) for the same services if furnished by a physician"

(d) Application of Limits on Billing.--Section 1842(b)(18)(C) (42 U.S.C. 1395u(b)(18)(C)) is amended by adding at the end the following new clause:

"(vi) A registered dietitian or nutrition professional.".

(e) Effective Date.--The amendments made by this section shall apply to services furnished on or after January 1, 2002.

(f) Study.--Not later than July 1, 2003, the Secretary of Health and Human Services shall submit to Congress a report that contains recommendations with respect to the expansion to other medicare beneficiary populations of the medical nutrition therapy services benefit (furnished under the amendments made by this section).

March 14, 2000

The American Medical Association/Specialty Society RVS Update Committee

PHYSICIAN/PROVIDER WORK RVS Update Survey

Tracking Numbers; New CPT Codes; and Descriptors

K1	978X1	Medical nutrition therapy initial assessment and intervention, low complexity
K2	978X2	Medical nutrition therapy initial assessment and intervention, moderate complexity
K3	978X3	Medical nutrition therapy initial assessment and intervention, high complexity
K4	978X4	Medical nutrition therapy reassessment and intervention, low complexity
K5	978X5	Medical nutrition therapy reassessment and intervention, moderate complexity
K6	978X6	Medical nutrition therapy reassessment and intervention, high complexity
K7	978X7	Medical nutrition therapy reassessment and intervention, low Complexity, group setting

Global Period: XXX for all seven codes

INTRODUCTION

Why should I complete this survey?

The AMA/Specialty Society RVS Update Committee (RUC) and The American Dietetic Association, the American Association of Clinical Endocrinologists, American Gastroenterological Association, and the Society of American Gastrointestinal Endoscopy needs your help to assure relative values will be accurately and fairly presented to HCFA during this revision process. This is important to you and other physician/providers because these values determine the rate at which Medicare and other payers reimburse for procedures.

What if I have a question?

Contact: Pam Michael, MBA, RD, LD; The American Dietetic Association, Director Health Care Financing Team; 800-877-1600, ext. 4844 or email: pmichae@eatright.org

How is this survey organized?

Each new code must be surveyed, there are 7 medical nutrition therapy (MNT) codes that are included in this one survey document. There are 7 questions in the survey relating to physician/provider work.

START HERE

The following information must be provided by the Physician/Provider responsible for completing the questionnaire.

Physician/Provider Name: [illegible]
Business Name: [illegible]
Business Address: [illegible]
City: [illegible]
State: NY
Zip: [illegible]
Business Phone: (212) 333 4243
Business Fax: (212) 333 3763
E-mail Address: ____
Physician/Provider Specialty: Nutrition
Years Practicing Specialty: 6

Primary Geographic Practice Setting: Rural____ Suburban____ Urban ✓

Primary Type of Practice:
Solo Practice____
Single Specialty Group ✓
Multispecialty Group____
Medical School Faculty Practice Plan____

PHYSICIAN/PROVIDER WORK

INTRODUCTION

"Physician/Provider work" includes the following elements:

- Physician/Provider time it takes to perform the service
- Physician/Provider mental effort and judgment
- Physician/Provider technical skill and physical effort, and
- Physician/Provider psychological stress that occurs when an adverse outcome has serious consequences

All of these elements will be explained in greater detail as you complete this survey.

"Physician/Provider work" does **not** include the services provided by support staff who are employed by your practice and cannot bill separately, including registered nurses, licensed practical nurses, medical secretaries, receptionists, and technicians; these services are included in the practice cost relative values, a different component of the RBRVS.

Medical Nutrition Therapy (MNT) Vignettes

The AMA RUC has indicated the following definitions apply to medical nutrition therapy initial assessment and reassessment codes (978X1-978X7)

K1 978X1 Medical nutrition therapy initial assessment and intervention, low complexity

Definition
Therapy with patient with one diagnosis, limited data to be reviewed, and low risk of nutrition-related complications.

Description of Procedure(s)/Service(s):
Review of the patient's medical record for medical diagnosis. Nutrition history from the patient, evaluation of use of nutrition supplements, identification of nutrition problems. Obtaining of physical measurements, calculations related to body size. Nutrition assessment to evaluate patient's current nutrition needs, appropriateness of weight in relation to desirable body weight and goal weight, adequacy of present diet, potential drug-nutrient interactions, exercise patterns; psychosocial food patterns; and patient's knowledge and willingness to implement nutrition interventions. Formulation of a nutrition prescription specific to patient's diagnosis, translation of nutrition prescription into an individualized meal plan and menu guidelines. Self-management training, review of techniques for self-monitoring, identification of self-management goals, and scheduling of a follow-up appointment. Documentation of nutrition assessment, nutrition prescription, and instructions provided in the patient's medical record.

A 42-year-old male has been diagnosed with hypertension. Initial medical nutrition therapy assessment and intervention is being initiated prior to a decision on whether to prescribe medication.

K2 978X2 Medical nutrition therapy initial assessment and intervention, moderate complexity

Definition
Therapy with patient with one or more medical diagnoses and comorbidities, with moderately complex data to be reviewed, and a high risk of nutrition-related complications.

Description of Procedure(s)/Service(s):
Thorough review of the patient's medical record for medical diagnosis, past medical history, history of present illness, and pertinent lab data. Nutrition history from the patient, thorough evaluation of nutrient intake and use of nutrition supplements, identification of nutrition problems. Obtaining of physical measurements, calculations related to body size. Intensive nutrition assessment to evaluate nutrient requirements, appropriateness of weight in relation to desirable body weight and goal weight, adequacy of present diet, potential drug-nutrient interactions, exercise patterns, psychosocial food patterns, and patient's knowledge of and willingness to implement nutrition interventions. Review of clinical data and lab information and evaluation of patient's ability to perform self-monitoring. Formulation of a complex nutrition prescription specific to patient's diagnosis, translation of nutrition prescription into an individualized meal plan and menu guidelines. Self-management training, review of techniques for self-monitoring, identification of self-management goals, identification of barriers to adherence and strategies to overcome barriers, and scheduling of follow-up appointment(s). Documentation of nutrition assessment, nutrition prescription, and self-management training provided in the patient's medical record, with notation of communication with other health care providers and any referrals made.

A 66-year-old female with pre-existing osteoporosis has been diagnosed with type 2 diabetes and hyperlipidemia. Initial medical nutrition therapy assessment and intervention is being initiated, in addition to oral medication for treatment of diabetes.

K3 978X3 Medical nutrition therapy initial assessment and intervention, high complexity

Definition
Therapy with patient with one or more medical diagnoses and comorbidities of a highly complex nature, with highly complex data to be reviewed, and a high risk of nutrition-related complications.

Description of Procedure(s)/Service(s):
Comprehensive review of the patient's medical record for diagnosis, past medical history, history of present illness, review of systems, medications, and lab data. Collaboration with physician and other health care providers. Comprehensive nutrition history from the patient, in-depth evaluation of nutrient intake, use of nutrition supplements, weight history, and identification of nutrition problems. Obtaining of physical measurements, physical assessment, calculations related to body size. Comprehensive nutrition assessment to evaluate nutrient requirements, appropriateness of weight in relation to desirable body weight and goal weight, adequacy of present diet or nutrition regimen, potential drug-nutrient interactions, exercise patterns, psychosocial food patterns, and patient's knowledge of and willingness to implement nutrition interventions. Review of clinical data and lab information and evaluation of patient's ability to perform self-monitoring. Formulation of a highly complex nutrition prescription from multiple nutrition management options and specific to patient's diagnosis, translation of nutrition prescription into an individualized meal plan and menu guidelines, or nutrition regimen. In-depth self-management training, review of techniques for self-monitoring, identification of self-management goals, identification of barriers to adherence and strategies to overcome barriers, and scheduling of follow-up appointment(s). Documentation of nutrition assessment, nutrition prescription, treatment protocol, and self-management training provided in the patient's medical record, with notation of communication with other health care providers and referrals made.

A 15-year-old female patient with uncontrolled non-insulin-dependent diabetes recently diagnosed with bulimia of 6 months' duration, who has experienced a 25-pound weight loss and has expressed a fear of getting fat. Patient purges 2 to 3 times per week, generally following a binge day. She is experiencing projectile vomiting, over which she no longer has control. Comprehensive medical nutrition therapy assessment and intervention are initiated for the patient.

K4 978X4 Medical nutrition therapy reassessment and intervention, low complexity

Definition
Therapy with patient with one diagnosis, limited data to be reviewed, and low risk of nutrition-related complications.

Description of Procedure(s)/Service(s):
Review of the patient's medical record. Nutrition history from patient, identification of changes in physician orders, identification of nutrition problems. Nutrition assessment to evaluate patient's adherence to nutrition prescription and meal plan, effectiveness of dietary modifications in medical management of diagnosis, changes in weight status, and need for additional nutrition interventions. Reinforcement self-management training on nutrition prescription, menu guidelines, and self-monitoring procedures. Definition of schedule for follow-up. Documentation of nutrition history, nutrition assessment, and reinforcement instructions provided in patient's medical record.

A 45-year-old woman with confirmed lactose intolerance who has received prior self-management training on a low lactose is seen for follow-up self-management training.

K5 978X5 Medical nutrition therapy reassessment and intervention, Moderate complexity

Definition
Therapy with patient with one or more medical diagnoses and comorbidities, with moderately complex data to be reviewed, and a high risk of nutrition-related complications.

Description of Procedure(s)/Service(s):
Review of the patient's medical record. Intensive nutrition history from patient, identification of changes in physician orders, identification of nutrition problems. Intensive nutrition assessment to evaluate patient's adherence to nutrition prescription and meal plan, barriers to adherence, medication schedule and lab data, effectiveness of dietary modifications in medical management of diagnoses, changes in weight status, and need for additional nutrition interventions. Reinforcement self-management training on nutrition prescription, menu guidelines, and self-monitoring procedures. Definition of schedule for follow-up. Documentation of nutrition history, nutrition assessment, reinforcement instructions provided, collaboration with other health care providers, and referrals made in patient's medical record.

A 67-year-old man with congestive heart failure with decreased cardiac output and edema who has received prior nutrition self-management training is receiving follow-up and more detailed self-management training to address co-morbidities.

K6 978X6 Medical nutrition therapy reassessment and intervention, high Complexity

Definition
Therapy with patient with one or more medical diagnoses and comorbidities of a highly complex nature, with highly complex data to be reviewed, and a high risk of nutrition-related complications.

Description of Procedure(s)/Service(s):
Review of the patient's medical record. Collaboration with physician or other health care providers. Comprehensive nutrition history from patient, identification of changes in physician orders, identification of nutrition problems, physical assessment of patient. Comprehensive nutrition assessment to evaluate patient's adherence to nutrition prescription, nutrition regimen, and meal plan, barriers to adherence, medication schedule and lab data, effectiveness of dietary modifications in medical management of diagnoses, changes in weight status, and need for additional nutrition interventions. Reinforcement self-management training on nutrition prescription and nutrition regimen, menu guidelines, medication schedule and administration, and self-monitoring procedures. Definition of schedule for follow-up. Documentation of nutrition history, nutrition assessment, reinforcement instructions provided, collaboration with other health care providers, and referrals made in the patient's medical record.

A 35-year-old female with gestational diabetes mellitus with excess weight gain during pregnancy who has received prior medical nutrition therapy intervention and requires highly comprehensive reassessment and complex intervention including the review of her nutrition prescription and diet guidelines and evaluation of her ability to make needed adjustments in her food selection and preparation.

K7 978X7 Medical nutrition therapy reassessment and intervention, low complexity, group setting

Definition
Therapy with patient with one diagnosis, limited data to be reviewed, and low risk of nutrition-related complications, group setting.

Description of Procedure(s)/Service(s):
Review of the patient's medical record. Nutrition history from the patient, identification of changes in physician orders, identification of nutrition problems. Nutrition assessment to evaluate patient's adherence to nutrition prescription and meal plan, effectiveness of dietary modifications in medical management of diagnosis, changes in weight status, and need for additional nutrition interventions. Skill development/self-management training in a small group setting on nutrition prescription, menu guidelines, and self-monitoring procedures. Definition of schedule for follow-up. Documentation of nutrition history, nutrition assessment, and instructions provided in patient's medical record.

A 55-year-old man with hyperlipidemia and obesity who has received prior face-to-face self-management training is receiving follow-up self-management training in a small group setting.

Background for Question 1

Attached is a list Reference Services that have been selected for use as comparison services for this survey because their relative values are sufficiently accurate and stable to compare with other services. The "2000 Work RVU" column presents current Medicare RBRVS work RVUs (relative value units). Select one code which is most similar to the new/revised CPT code descriptor and typical patient/service described on the cover of this questionnaire.

Note: The American Medical Association advised that the global period for medical nutrition therapy codes is XXX and reference service list global periods are XXX.

It is very important to consider the global period when you are comparing the new code to the reference services. A service paid on a global basis includes:

- visits and other physician/provider services provided within 24 hours prior to the service;
- provision of the service; and
- visits and other physician/provider services for a specified number of days after the service is provided.

The global periods listed on the cover of the survey refer to the number of post-service days of care that are included in the payment for the service as determined by the Health Care Financing Administration for Medicare payment purposes.

Categories of *Global Period:*

090 90 days of post-service care are included in the work RVU

010 10 days of post-service care are included in the work RVU

000 0 days of post-service care are included in the work RVU

ZZZ This code is reported in addition to a primary procedure and only the additional intra-service work to perform this service is included in the work RVU

XXX A global period does not apply to the code and evaluation and management and other diagnostic tests or minor services performed, may be reported separately on the same day

QUESTION 1: Which of the Reference Service List, see Attachment #1, is most similar to the new CPT Code Descriptor and Typical Patient Service described on the cover of this questionnaire?

K1 978X1 Medical nutrition therapy initial assessment and intervention- Low complexity: CPT Code 99244
K2 978X2 Medical nutrition therapy initial assessment and intervention- Moderate complexity: CPT Code 99245
K3 978X3 Medical nutrition therapy initial assessment and intervention- High complexity: CPT Code 99245 AND 99354
K4 978X4 Medical nutrition therapy reassessment and intervention- Low complexity: CPT Code 99213
K5 978X5 Medical nutrition therapy reassessment and intervention- Moderate complexity: CPT Code 99214
K6 978X6 Medical nutrition therapy reassessment and intervention- High complexity: CPT Code 99215
K7 978X7 Medical nutrition therapy reassessment and intervention- Low complexity, group setting: CPT Code 99214

BACKGROUND FOR QUESTION 2
SERVICE PERIOD DESCRIPTIONS

OFFICE

PRE-SERVICE PERIOD

The pre-service period includes services provided before the service and may include preparing to see the patient, reviewing records, and communicating with other professionals.

INTRA-SERVICE PERIOD

The intra-service period includes the services provided while you are with the patient and/or family. This includes the time in which the physician obtains the history, performs an evaluation, and counsels the patient.

POST-SERVICE PERIOD

The post-service period includes services provided after the service and may include arranging for further services, reviewing results of studies, and communicating further with the patient, family, and other professionals which includes written and telephone reports.

HOSPITAL

PRE-SERVICE PERIOD

The pre-service period includes services that are **not performed on the patient's hospital unit or floor**, including: communications with other professionals and the patient's family; obtaining and/or reviewing the results of diagnostic and other studies; and written and telephone reports.

INTRA-SERVICE PERIOD

The intra-service period includes the services provided while you are present on the patient's hospital unit or floor, including: reviewing the patient's chart; seeing the patient, writing notes, and communicating with other professionals and the patient's family.

POST-SERVICE PERIOD

The post-service period includes services that are not provided on the patient's hospital unit or floor, including: communicating further with other professionals and the patient's family; obtaining and/or reviewing the results of diagnostic and other studies; and written and telephone reports.

QUESTION 2: How much of <u>your</u> own time is required per patient treated for each of the following steps in patient care related to this procedure? Indicate your time for both the new code on the front cover and the reference you chose in Question 1.
(Refer to pre-, intra- and post-service definitions on page 11.)

K1 978X1 Medical nutrition therapy initial assessment and intervention- Low complexity :

Day of Procedure

	New Code	Reference Code
Pre-service time:	5 min	5 min
Intra-service time:	60 min	60 min
Post-service time:	15 min	15 min

K2 978X2 Medical nutrition therapy initial assessment and intervention- Moderate complexity:

Day of Procedure

	New Code	Reference Code
Pre-service time:	10 min	10 min
Intra-service time:	30 min	30 min
Post-service time:	10 min	10 min

K3 978X3 Medical nutrition therapy initial assessment and intervention- High complexity:

Day of Procedure

	New Code	Reference Code
Pre-service time:	15 min	15 min
Intra-service time:	120 min	120 min
Post-service time:	15 min	15 min

K4 978X4 Medical nutrition therapy reassessment and intervention- Low complexity:

Day of Procedure

	New Code	Reference Code
Pre-service time:	5 min	5 min
Intra-service time:	15 min	15 min
Post-service time:	5 min	5 min

QUESTION 2, continued:

K5 978X5 Medical nutrition therapy reassessment and intervention- Moderate complexity:

Day of Procedure

	New Code	Reference Code
Pre-service time:	5 min	5 min
Intra-service time:	25 min	25 min
Post-service time:	5 min	1 min

K6 978X6 Medical nutrition therapy reassessment and intervention- High complexity:

Day of Procedure

	New Code	Reference Code
Pre-service time:	5 min	5 min
Intra-service time:	40 min	40 min
Post-service time:	5 min	5 min

K7 978X7 Medical nutrition therapy reassessment and intervention- Low complexity, group setting:

Day of Procedure

	New Code	Reference Code
Pre-service time:	5 min	5 min
Intra-service time:	25 min	25 min
Post-service time:	5 min	1 min

QUESTION 3: For the New CPT codes and for the reference services you chose, rate the AVERAGE pre-, intra-, and post service *complexity/intensity* on a scale of 1 to 5 (circle one: 1 = low; 3 medium 5 = high)

K1 978X1 Medical nutrition therapy initial assessment and intervention- Low complexity:		
	New CPT:	Reference Service CPT:
PRE-service	1 2 (3) 4 5	1 2 (3) 4 5
INTRA-service	1 2 (3) 4 5	1 2 (3) 4 5
POST-service	1 2 (3) 4 5	1 2 (3) 4 5

K2 978X2 Medical nutrition therapy initial assessment and intervention- Moderate complexity:		
	New CPT:	Reference Service CPT:
PRE-service	1 2 3 (4) 5	1 2 3 (4) 5
INTRA-service	1 2 3 (4) 5	1 2 3 (4) 5
POST-service	1 2 3 (4) 5	1 2 3 (4) 5

K3 978X3 Medical nutrition therapy initial assessment and intervention-High complexity :		
	New CPT:	Reference Service CPT:
PRE-service	1 2 3 4 (5)	1 2 3 4 (5)
INTRA-service	1 2 3 4 (5)	1 2 3 4 (5)
POST-service	1 2 3 4 (5)	1 2 3 4 (5)

K4 978X4 Medical nutrition therapy reassessment and Intervention-Low complexity:		
	New CPT:	Reference Service CPT:
PRE-service	1 2 (3) 4 5	1 2 (3) 4 5
INTRA-service	1 2 (3) 4 5	1 2 (3) 4 5
POST-service	1 2 (3) 4 5	1 2 (3) 4 5

K5 978X5 Medical nutrition therapy reassessment and intervention-Moderate complexity:		
	New CPT:	Reference Service CPT:
PRE-service	1 2 3 (4) 5	1 2 3 (4) 5
INTRA-service	1 2 3 (4) 5	1 2 3 (4) 5
POST-service	1 2 3 (4) 5	1 2 3 (4) 5

QUESTION 3, continued:

K6 978X6 Medical nutrition therapy reassessment and intervention- High complexity:		
	New CPT:	Reference Service CPT:
PRE-service	1 2 3 4 (5)	1 2 3 4 (5)
INTRA-service	1 2 3 4 (5)	1 2 3 4 (5)
POST-service	1 2 3 4 (5)	1 2 3 4 (5)
K7 978X7 Medical nutrition therapy reassessment and intervention- Low complexity, group setting:		
	New CPT:	Reference Service CPT:
PRE-service	1 2 3 (4) 5	1 2 3 (4) 5
INTRA-service	1 2 3 (4) 5	1 2 3 (4) 5
POST-service	1 2 3 (4) 5	1 2 3 (4) 5

Background for Question 4

In evaluating the work of a service, it is helpful to identify and think about each of the components of a particular service. Focus only on the work that **you** perform during each of the identified components. The descriptions below are general in nature. Within the broad outlines presented, please think about the specific services that you provide.

Physician/Provider work includes the following:

Time it takes to perform the service.

Mental Effort and Judgment necessary with respect to the amount of clinical data that needs to be considered, the fund of knowledge required, the range of possible decisions, the number of factors considered in making a decision, and the degree of complexity of the interaction of these factors.

Technical Skill required with respect to knowledge, training and actual experience necessary to perform the service.

Physical Effort can be compared by dividing services into tasks and making the direct comparison of tasks. In making the comparison, it is necessary to show that the differences in physical effort are not reflected accurately by differences in the time involved; if they are, considerations of physical effort amount to double counting of physician/provider work in the service.

Psychological Stress – Two kinds of psychological stress are usually associated with physician/provider work. The first is the pressure involved when the outcome is heavily dependent upon skill and judgment and an adverse outcome has serious consequences. The second is related to unpleasant conditions connected with the work that are not affected by skill or judgment. These circumstances would include situations with high rates of mortality or morbidity regardless of the physician/provider's skill or judgment, difficult patients or families, or physician/provider physical discomfort. Of the two forms of stress, only the former is fully accepted as an aspect of work; many consider the latter to be a highly variable function of physician/provider personality.

QUESTION 4: For the New CPT codes and for the reference services you chose, rate the intensity for each component listed on a scale of 1 to 5. (circle one: 1= low; 3 medium 5 = high)

K1 978X1 Medical nutrition therapy initial assessment and intervention- Low complexity

Mental Effort and Judgment	New CPT:	Ref. Service CPT:
The range of possible diagnoses and/or management options that must be considered	1 2 (3) 4 5	1 2 (3) 4 5
The amount and/or complexity of medical records, diagnostic tests, or other information that must be analyzed	1 2 (3) 4 5	1 2 (3) 4 5
Urgency of medical decision making	1 2 (3) 4 5	1 2 (3) 4 5
Technical Skill/Physical Effort		
Technical skill required	1 2 (3) 4 5	1 2 (3) 4 5
Physical effort required	1 2 (3) 4 5	1 2 (3) 4 5
Psychological Stress		
The risk of significant complications, morbidity and/or mortality	1 2 (3) 4 5	1 2 (3) 4 5
Outcome depends on skill and judgment of Physician/Provider	1 2 (3) 4 5	1 2 (3) 4 5
Estimated risk of malpractice suit with poor outcome	1 2 (3) 4 5	1 2 (3) 4 5

K2 978X2 Medical nutrition therapy initial assessment and intervention- Moderate complexity

Mental Effort and Judgment	NEW CPT:	Ref. Service CPT:
The range of possible diagnoses and/or management options that must be considered	1 2 3 (4) 5	1 2 3 (4) 5
The amount and/or complexity of medical records, diagnostic tests, or other information that must be analyzed	1 2 3 (4) 5	1 2 3 (4) 5
Urgency of medical decision making	1 2 3 (4) 5	1 2 3 (4) 5
Technical Skill/Physical Effort		
Technical skill required	1 2 3 (4) 5	1 2 3 (4) 5
Physical effort required	1 2 3 (4) 5	1 2 3 (4) 5
Psychological Stress		
The risk of significant complications, morbidity and/or mortality	1 2 3 (4) 5	1 2 3 (4) 5
Outcome depends on skill and judgment of Physician/Provider	1 2 3 (4) 5	1 2 3 (4) 5
Estimated risk of malpractice suit with poor outcome	1 2 3 (4) 5	1 2 3 (4) 5

Question 4, continued

K3 978X3 Medical nutrition therapy initial assessment and intervention-High complexity		
Mental Effort and Judgment	NEW CPT:	Ref. Service CPT:
The range of possible diagnoses and/or management options that must be considered	1 2 3 4 (5)	1 2 3 4 (5)
The amount and/or complexity of medical records, diagnostic tests, or other information that must be analyzed	1 2 3 4 (5)	1 2 3 4 (5)
Urgency of medical decision making	1 2 3 4 (5)	1 2 3 4 (5)
Technical Skill/Physical Effort		
Technical skill required	1 2 3 4 (5)	1 2 3 4 (5)
Physical effort required	1 2 3 4 (5)	1 2 3 4 (5)
Psychological Stress		
The risk of significant complications, morbidity and/or mortality	1 2 3 4 (5)	1 2 3 4 (5)
Outcome depends on skill and judgment of Physician/Provider	1 2 3 4 (5)	1 2 3 4 (5)
Estimated risk of malpractice suit with poor outcome	1 2 3 4 (5)	1 2 3 4 (5)

K4 978X4 Medical nutrition therapy reassessment and intervention-Low complexity		
Mental Effort and Judgment	New CPT:	Ref. Service CPT:
The range of possible diagnoses and/or management options that must be considered	1 2 (3) 4 5	1 2 (3) 4 5
The amount and/or complexity of medical records, diagnostic tests, or other information that must be analyzed	1 2 (3) 4 5	1 2 (3) 4 5
Urgency of medical decision making	1 2 (3) 4 5	1 2 (3) 4 5
Technical Skill/Physical Effort		
Technical skill required	1 2 (3) 4 5	1 2 (3) 4 5
Physical effort required	1 2 (3) 4 5	1 2 (3) 4 5
Psychological Stress		
The risk of significant complications, morbidity and/or mortality	1 2 (3) 4 5	1 2 (3) 4 5
Outcome depends on skill and judgment of Physician/Provider	1 2 (3) 4 5	1 2 (3) 4 5
Estimated risk of malpractice suit with poor outcome	1 2 (3) 4 5	1 2 (3) 4 5

Question 4, continued

K5 978X5 Medical nutrition therapy reassessment and intervention-Moderate complexity		
Mental Effort and Judgment	**New CPT:**	**Ref. Service CPT:**
The range of possible diagnoses and/or management options that must be considered	1 2 3 (4) 5	1 2 3 (4) 5
The amount and/or complexity of medical records, diagnostic tests, or other information that must be analyzed	1 2 3 (4) 5	1 2 3 (4) 5
Urgency of medical decision making	1 2 3 (4) 5	1 2 3 (4) 5
Technical Skill/Physical Effort		
Technical skill required	1 2 3 (4) 5	1 2 3 (4) 5
Physical effort required	1 2 3 (4) 5	1 2 3 (4) 5
Psychological Stress		
The risk of significant complications, morbidity and/or mortality	1 2 3 (4) 5	1 2 3 (4) 5
Outcome depends on skill and judgment of Physician/Provider	1 2 3 (4) 5	1 2 3 (4) 5
Estimated risk of malpractice suit with poor outcome	1 2 3 (4) 5	1 2 3 (4) 5

K6 978X6 Medical nutrition therapy reassessment and intervention-High complexity		
Mental Effort and Judgment	**New CPT:**	**Ref. Service CPT:**
The range of possible diagnoses and/or management options that must be considered	1 2 3 4 (5)	1 2 3 4 (5)
The amount and/or complexity of medical records, diagnostic tests, or other information that must be analyzed	1 2 3 4 (5)	1 2 3 4 (5)
Urgency of medical decision making	1 2 3 4 (5)	1 2 3 4 (5)
Technical Skill/Physical Effort		
Technical skill required	1 2 3 4 (5)	1 2 3 4 (5)
Physical effort required	1 2 3 4 (5)	1 2 3 4 (5)
Psychological Stress		
The risk of significant complications, morbidity and/or mortality	1 2 3 4 (5)	1 2 3 4 (5)
Outcome depends on skill and judgment of Physician/Provider	1 2 3 4 (5)	1 2 3 4 (5)
Estimated risk of malpractice suit with poor outcome	1 2 3 4 (5)	1 2 3 4 (5)

Question 4, continued

K7 978X7 Medical nutrition therapy reassessment and intervention-Low complexity, group setting

Mental Effort and Judgment	New CPT:	Ref. Service CPT:
The range of possible diagnoses and/or management options that must be considered	1 2 3 (4) 5	1 2 3 (4) 5
The amount and/or complexity of medical records, diagnostic tests, or other information that must be analyzed	1 2 3 (4) 5	1 2 3 (4) 5
Urgency of medical decision making	1 2 3 (4) 5	1 2 3 (4) 5
Technical Skill/Physical Effort		
Technical skill required	1 2 3 (4) 5	1 2 3 (4) 5
Physical effort required	1 2 3 (4) 5	1 2 3 (4) 5
Psychological Stress		
The risk of significant complications, morbidity and/or mortality	1 2 3 (4) 5	1 2 3 (4) 5
Outcome depends on skill and judgment of Physician/Provider	1 2 3 (4) 5	1 2 3 (4) 5
Estimated risk of malpractice suit with poor outcome	1 2 3 (4) 5	1 2 3 (4) 5

QUESTION 5: How many times have you personally performed these procedures in the past year?

K1 978X1 Medical nutrition therapy initial assessment and intervention- Low complexity: How many times have you personally performed these procedures in the past year? New Code: 0 Reference Service Code: 0
K2 978X2 Medical nutrition therapy Initial assessment and intervention- Moderate complexity: How many times have you personally performed these procedures in the past year? New Code: 100 Reference Service Code: 100
K3 978X3 Medical nutrition therapy initial assessment and intervention- High complexity: How many times have you personally performed these procedures in the past year? New Code: 300 Reference Service Code: 300
K4 978X4 Medical nutrition therapy reassessment and intervention- Low complexity: How many times have you personally performed these procedures in the past year? New Code: 0 Reference Service Code: 0
K5 978X5 Medical nutrition therapy reassessment and intervention- Moderate complexity: How many times have you personally performed these procedures in the past year? New Code: 100 Reference Service Code: 100
K6 978X6 Medical nutrition therapy reassessment and intervention- High complexity: How many times have you personally performed these procedures in the past year? New Code: 300 Reference Service Code: 300
K7 978X7 Medical nutrition therapy reassessment and intervention-Low complexity, group setting: How many times have you personally performed these procedures in the past year? New Code: 0 Reference Service Code: 0

Question 6: Is your typical patient for this procedure similar to the medical nutrition therapy vignette, found on pages 3-7, in the survey?

K1 97X1 Medical nutrition therapy initial assessment and intervention- Low complexity Is your typical patient for this procedure similar to the medical nutrition therapy vignette, found on pages 3-7, in the survey? Yes ? (No ?) If no, please describe your typical patient for this procedure: DO NOT SEE LOW-COMPLEXITY PATIENTS
K2 97X2 Medical nutrition therapy initial assessment and intervention- Moderate complexity Is your typical patient for this procedure similar to the medical nutrition therapy vignette, found on pages 3-7, in the survey? (Yes ?) No ? If no, please describe your typical patient for this procedure:
K3 97X3 Medical nutrition therapy initial assessment and intervention-High complexity Is your typical patient for this procedure similar to the medical nutrition therapy vignette, found on pages 3-7 in the survey? (Yes ?) No ? If no, please describe your typical patient for this procedure:
K4 97X4 Medical nutrition therapy reassessment and intervention-Low complexity Is your typical patient for this procedure similar to the medical nutrition therapy vignette, found on pages 3-7 in the survey? Yes ? (No ?) If no, please describe your typical patient for this procedure: DO NOT SEE LOW-COMPLEXITY PATIENTS
K5 97X5 Medical nutrition therapy reassessment and intervention-Moderate complexity Is your typical patient for this procedure similar to the medical nutrition therapy vignette, found on pages 3-7 in the survey? (Yes ?) No ? If no, please describe your typical patient for this procedure:
K6 97X6 Medical nutrition therapy reassessment and intervention-High complexity Is your typical patient for this procedure similar to the medical nutrition therapy vignette, found on pages 3-7 in the survey? (Yes ?) No ? If no, please describe your typical patient for this procedure:
K7 97X7 Medical nutrition therapy reassessment and intervention-Low complexity, group setting Is your typical patient for this procedure similar to the medical nutrition therapy vignette, found on pages 3-7 in the survey? Yes ? (No ?) If no, please describe your typical patient for this procedure: DO NOT SEE PATIENTS IN GROUP SETTINGS

**********VERY IMPORTANT**********

QUESTION 7:

K1 978X1 Medical nutrition therapy initial assessment and intervention- Low complexity **Based on your review of all previous steps, please provide your Estimate work RVU for the new CPT code:** 1.6 RVUs
K2 978X2 Medical nutrition therapy initial assessment and intervention- Moderate complexity **Based on your review of all previous steps, please provide your Estimate work RVU for the new CPT code:** 3 RVUs
K3 978X3 Medical nutrition therapy initial assessment and intervention-High complexity **Based on your review of all previous steps, please provide your Estimate work RVU for the new CPT code:** 3 RVUs
K4 978X4 Medical nutrition therapy reassessment and intervention-Low complexity **Based on your review of all previous steps, please provide your Estimate work RVU for the new CPT code:** 3 RVUs
K5 978X5 Medical nutrition therapy reassessment and intervention-Moderate complexity **Based on your review of all previous steps, please provide your Estimate work RVU for the new CPT code:** 3 RVUs
K6 978X6 Medical nutrition therapy reassessment and intervention-High complexity **Based on your review of all previous steps, please provide your Estimate work RVU for the new CPT code:** 3 RVUs
K7 978X7 Medical nutrition therapy reassessment and intervention-Low complexity, group setting **Based on your review of all previous steps, please provide your Estimate work RVU for the new CPT code:** 3 RVUs

For example, if the new/revised code involves the same amount of physician/provider work as the reference service you choose, you would assign the same work RVU. If the new/revised code involves twice as much (or half as much) work as the reference service, you would calculate and assign a work RVU value that is twice as much (or half as much) as the work RVU of the reference service. This methodology attempts to set the work RVU of the new or revised service relative to the work RVU of comparable and established reference services.

Attachment F - Page 24 of 24

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ACADEMY OF MOLECULAR IMAGING
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September 14, 2006

SEP 15 2006

The Honorable Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1321-P

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007; DRA Proposals

Dear Administrator McClellan:

The Academy of Molecular Imaging (AMI) is pleased to have the opportunity to comment on the proposed rule, CMS-13210P, Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007, published in the Federal Register on August 22, 2006. The AMI is comprised of academicians, researchers and nuclear medicine physicians utilizing Positron Emission Tomography (PET) technology. AMI serves as the focal point for PET education, training, research and clinical practice through its annual scientific meeting, educational programs, and its Journal, *Molecular Imaging & Biology*. AMI speaks for thousands of physicians, scientists, and patients with regard to this lifesaving technology.

AMI is concerned that, as the result of the proposed reductions under the Deficit Reduction Act of 2005 (DRA), the provision of PET with computed tomography (PET/CT) will no longer be economically viable for many independent diagnostic testing facilities (IDTFs)—a result that would significantly limit beneficiary access to this vital technology. The scope of the proposed DRA cuts is deep and far reaching, and applies to both diagnostic and therapeutic imaging. AMI believes that the proposed reductions in the payment rate for PET/CT are not supported by the language of the statute. In addition, because there is no statutory basis on which to conclude that Congress intended to cut payments for therapeutic imaging in particular, AMI respectfully requests that the Centers for Medicare & Medicaid Services (CMS) clarify that PET/CT scans provided for the purpose monitoring cancer therapy are not subject to the payment limitation imposed by Section 5102 of the DRA.

Background on PET/CT

PET is a highly sensitive imaging technique for the detection of actively growing cancer cells. The key to PET's effectiveness is its ability to provide physicians with information about the body's chemistry, cell function and tissue metabolism that traditional anatomic imaging modalities do not offer. With anatomic imaging, the detection of a malignancy requires the use of successive scans to measure a lesion's rate of growth. By contrast, PET identifies the presence of malignancy by detecting abnormal tissue metabolism, often at a point in time when anatomic imaging scans still appear normal.

The fusion of PET and CT into a single imaging modality, known as PET/CT, offers the most complete non-invasive information available on cancer location and metabolism. By seamlessly merging PET and CT images, PET/CT can identify and localize tumors more accurately than either of the component modalities taken alone. PET/CT distinguishes between malignant and benign processes and reveals tumors that may otherwise be obscured by the scarring that often results from surgery, radiation, and drug therapy. The benefits to patients are tremendous: earlier diagnosis, more accurate staging, more precise treatment planning, better monitoring of therapy, and a reduction in the number of invasive procedures, such as biopsies.

PET/CT is an integral and vital component of cancer therapy. Cancerous tumors frequently change shape or move slightly during the course of treatment. Oncologists often adjust their initial treatment regimen based on the results of periodic PET/CT scans. Scans conducted for therapeutic monitoring thus enable oncologists to better target the cancer and to spare non-cancerous tissue from unnecessary and potentially harmful radiation. This integration of routine imaging into patients' therapeutic regimens has significantly enhanced the quality and precision of cancer treatment.

The Deficit Reduction Act of 2005

The Physician Fee Schedule (PFS) uses a resource-based relative value scale to calculate payments to physicians. That scale incorporates values for physician work, practice expense, and malpractice. The value assigned to imaging services performed in a physician's office under the PFS is generally significantly higher that the value assigned to the same services under the Hospital Outpatient Prospective Payment System (HOPPS).

Section 5102 of the DRA includes two provisions that reduce Medicare payments for imaging services. First, it caps the Medicare payment rate for the "technical" component (as distinguished from the "professional," or interpretive, component) for imaging procedures performed in a physician's office at the rate paid to hospital outpatient departments under the HOPPS.[1] Our comment focuses on this provision. Second, the

[1] DRA, § 5102(b)(1), Pub. L. 109-171 (Feb. 8, 2006).

DRA exempts from Medicare budget neutrality requirements scheduled reductions for imaging services performed on contiguous body parts during the same procedure.[2] The DRA defines imaging services to include "X-ray, ultrasound (including echocardiography), nuclear medicine (including position emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography."[3]

Neither the original House nor Senate version of the DRA included any provision reducing Medicare payments for imaging services. In fact, cuts to imaging services were never directly addressed by either chamber, and Section 5102 was added to the bill only by the conference committee.[4] Because the legislative record is silent with respect to Congress' intent, CMS should construe the provisions relating to imaging narrowly and with particular caution. AMI is working with professional societies, patients' advocates, and other stakeholders to develop legislation that would delay the implementation of the DRA for two years, until the issue can be further studied and the consequences for Medicare beneficiaries better known.

The DRA-Imposed Cap on Medicare Payment for Imaging Services Does not Apply to PET/CT

Section 5102 of the DRA, which caps Medicare payment for imaging services paid under the PFS at the rate paid to hospital outpatient departments, does not apply to PET/CT. The DRA reduces payment only for imaging services that are paid under the PFS. Section 5102 clearly states that imaging cuts apply to "*the technical component (including the technical component portion of a global fee) of the service established for a year under the fee schedule.*" However, PET/CT is one of the few imaging services for which the Medicare payment rate is not established by the PFS. Rather, in 2006 and previous years, rates were set by Medicare regional carriers. The flexibility of this policy allowed carriers to account for regional variations in the cost of providing PET/CT.

In the proposed rule CMS notes that the agency "*included carrier priced services since these services are within the statutory definition of imaging services and are also within the statutory definition of PFS services (that is, carrier-priced TCs of PET scans).*" In fact, CMS provides no compelling statutory basis for its decision to extend Section 5102 beyond the scope of services defined in Section 5102, to carrier-priced imaging services such as PET/CT. To the contrary, as we discuss below, the exclusion of carrier-priced services from the DRA-imposed payment cap is strongly supported by both the unique severity of such cuts for PET/CT services relative to other imaging services, as well as the devastating impact that such cuts would have on IDTFs.

The Proposed Payment Rate Reductions for PET/CT Will Have a Devastating Financial Impact on IDTFs

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[2] DRA, § 5102(a)(3)(v)(I), Pub. L. 109-171 (Feb. 8, 2006).
[3] DRA, § 5102(b)(1), Pub. L. 109-171 (Feb. 8, 2006).
[4] *See* Conference Report on S. 1932, Deficit Reduction Act of 2005 (House or Representatives, December 18, 2005).

AMERICAN COLLEGE OF CHEST PHYSICIANS

September 21, 2006

Mark B. McClellan, MD, PhD
Adminstrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P, Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: **CMS-1321-P** Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

American College of Chest Physicians Comments address: SGR and proposed negative
(-5.1%) update of the conversion factor; Multiple Imaging Procedure proposed reduction of all practice expense values by 0.3 percent; Therapy Cap

Dear Dr. McClellan:

I am submitting these comments on behalf of the American College of Chest Physicians (ACCP). The ACCP is comprised of over 16,500 physicians and allied health professionals, whose everyday practice involves diseases of the chest in the specialties of pulmonology, cardiology, thoracic and cardiovascular surgery, critical care medicine, sleep, and anesthesiology. These health care professionals practice in virtually every hospital in this country, and many of the physicians head major departments in these hospitals. As a multidisciplinary society, the ACCP offers broad viewpoints on matters of public health and clinical policy in cardiopulmonary medicine and surgery.

The ACCP appreciates the opportunity to submit comments for consideration on the CMS second proposed rule regarding Medicare's proposed revisions to payment policies under the Physician Fee Schedule for calendar year 2007 and other changes to payment under Part B published on August 22, 2006.

SUSTAINABLE GROWTH RATE (SGR) AND PROPOSED 5.1% Cut

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www.chestnet.org

As expected, a 5.1 % across the board cut of the conversion factor in Medicare physician payments was announced in this rule. Previously, Congress has intervened to put the SGR formula aside and mandate a Medicare conversion factor. ACCP still strongly believes that the SGR formula is seriously flawed and needs to be replaced. The affects of the SGR cannot continue to be fixed on an annual basis, since the SGR is the source of the problem for the yearly negative updates to the MPFS. CMS continues to underestimate the impact of National and Local Coverage Decisions on increased spending on physician services under Medicare. Even though we applaud the proposed addition of the abdominal aortic aneurysm ultrasound test to the Welcome to Medicare visit, it highlights the need for additional money added to the MPFS for all the ancillary costs associated with new preventive benefits such as this.

As said in our recent letter, we strongly support the removal of the costs of Medicare-covered physician-administered drugs from the SGR calculation. CMS needs to use its discretionary authority to remove the costs of Medicare-covered physician-administered drugs from the SGR calculation, which have increased from $1.8 billion in 1996 to $8.6 billion in 2004 and an estimated $8.2 billion in 2005. Nearly all of the medical community has commented on this issue and remains frustrated that the SGR-adjustment to the Medicare physician fee schedule has not been made.

MULTIPLE IMAGING PROCEDURE REBATE

The fact that CMS proposes to count the 0.3% budget savings, as the Deficit Reduction Act's requirement to cap payments for multiple imaging services as part of budget savings, is not a good strategy. We appreciate Medicare's new policy of being transparent and read in the previous proposed rule (CMS-1512-PN) page 37250, that the practice expenses are reduced in total by one-third.

We recommend that the 0.3% budget savings be included in the one-third practice expenses that physicians are not given, rather than be taken from the two-thirds practice expenses that physicians are paid.

THERAPY CAP

Some pulmonology practices employ physical therapists for their pulmonary rehabilitation programs. In the outpatient setting, CMS has placed an overall limitation on Medicare spending for physical, occupational and speech therapists. The patient is responsible for costs above the current limit of $1,740, which is proposed to increase by $50 ($1790). The exceptions process for medical necessity that is in place for 2006 will be terminated on December

Submitter : Mr. Bradley Schmidt
Organization : Inglewood Imaging Center, LLC
Category : Health Care Provider/Association
Date: 09/15/2006

Issue Areas/Comments

GENERAL

GENERAL

September 15, 2006

Medicare:

The reason for my request is probably a little more self-serving. I am opening a new outpatient imaging center in Inglewood, CA later this year and Medicare is threatening the project by reducing the payment rates by almost 70% from this year fee schedule to next years by assuming a single payment standard for hospitals and outpatient imaging centers. Therefore I wanted to go directly to THE healthcare source and express my frustration with Medicare proposed payment changes and give you an overview of what IDTF s face in opening up a non-referral diagnostic center

FINANCIAL IMPACT OF START UP
Opening as an IDTF, was a very difficult decision. For starters, Medicare puts undo regulations on an IDTF s mandating a supervision to be onsite (costing an additional $1,000/day to have a radiologist onsite). Second, IDTF s don t have a guarantee of securing payor contracts as is the case with medical practices. So it is totally possible all local payors will not contract services with our IDTF as their network might be full. Third, I was actually planning for a drop in reimbursement by discounting 25% from current Medicare rates. Medicare was communicating they wanted to drop rates, earlier this year so I felt the 25% was a worst case scenario. Forth, to make these numbers work I had to buy a used MRi (very good technology) and negotiate very hard with our vendor to bring our PET/CT price down to $1,688,000. I honestly would have loved to buy a new MRi but the decrease in reimbursement would not allow this luxury. Finally, I had to reduce the center s personnel. It would have been great to hire a phlebotomist, sales representative, and an IT manager, but because of the decrease in reimbursement I will be assuming their roles.

A HOSPITAL FEE SCHEDULE SHOULD NOT BE THE SAME AS AN IDTF
Hospital services generate additional fees that are not found at IDTF s. Patients are referred for one scan and one cost so the expense of service was a lot less than found at hospitals. Yet, the current landscape may show IDTF s to be paid at the same rate of hospitals which doesn t make sense since the hospital charges for so many extra tests. Also if the hospital fee schedule is passes, it will reduce our outpatient revenue by upwards of 70%! This drop in reimbursement will surly hurt many more facilities.

POTENTIAL ALTERNATIVES TO REDUCE COSTS
I understand Medicare need to reduce costs, but they are going about it in the wrong way. I would recommend the following solutions:
1. Mandate a certain technology requirement in order to be paid for imaging tests - such as 5 onsite modalities. This would curb the incentive for self-referral and reduce costs.
2. Maintain the existing IDTF fee schedule separate from a hospitals fee schedule.
3. Understand technology changes and pay a reimbursement premium for such.
4. Refer patients to the best modality possible for specific diseases. The current rules mandate many unnecessary test prior to getting the best test.
5. Increase the payment rates to Hospitals for services performed. It would be great if they were not in this situation.

CONCLUSION
Medical technologies reduce unnecessary medical procedures, pin-point diseases faster; offer an improved course of treatment, and save costs. Yet, the change in Medicare payment structure and rates will kill the industry (for lack of a better word).

I know that I am biased, but diagnostic imaging tests are THE FUTURE of healthcare. I would love to sit and discuss.

Sincerely,

Bradley Schmidt
CEO, Inglewood Imaging Center LLC
415-710-7070 (mobile)

NASSAU SURGICAL
ASSOCIATES, P.C.
GENERAL SURGERY • BREAST SURGERY • LAPAROSCOPIC SURGERY

Michael E. Khalife, M.D., F.A.C.S.
Diplomate American Board of Surgery
Assistant Clinical Professor of Surgery SUNY Stony Brook

David K. Halpern, M.D., F.A.C.S.
Diplomate American Board of Surgery
Assistant Clinical Professor of Surgery, SUNY Stony Brook

September 15, 2006

Office of the Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B

Dear Administrator:

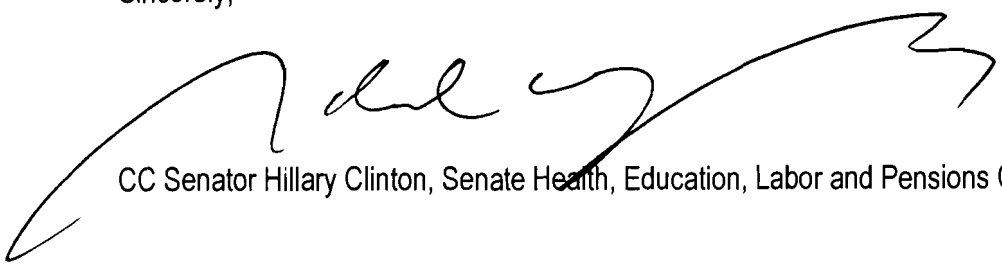
Thank you for allowing me the opportunity to provide comment on the Centers for Medicare and Medicaid Services' proposed rule, published in the Federal Register on August 22, 2006. This letter is written to share my concern regarding the proposed RVU reduction for CPT19296, performed in-office, over the next few years.

The proposed reduction of the conversion factor by 5.1%,which I am aware is tied to the cost of living, in conjunction with an RVU decrease will negatively impact medicare beneficiaries.

Access to partial breast irradiation (PBI) is crucial for many patients. With a breast cancer diagnosis, it is imperative the tumor is removed and radiation therapy start as quickly as possible. PBI allows this process to move very quickly so that other treatments (chemotherapy) can be started as well. Unfortunately, if the proposed reduction takes place, I may no longer be able to provide PBI to my Medicare patients; therefore limiting access to treatments for this deadly disease. As a result, my Medicare patients may be required to have services scheduled at the hospital which will add a greater cost to the Medicare system, as well as impede quick access and scheduling for patients with a confirmed diagnosis of breast cancer.

I am a practitioner focusing on breast cancer treatment, I strongly urge CMS to reconsider the proposed RVU reductions. I recommend preserving RVUs system , and if needed, make reductions to the conversion factor. I appreciate your careful consideration and review in this important matter and strongly urge CMS to reconsider the significant impact of the proposal.

Sincerely,



CC Senator Hillary Clinton, Senate Health, Education, Labor and Pensions Committee

22

Srinivas S.Vasireddi,M.D.,FACP
Diplomate American Board of Gastroenterology

To

Mark McClellan,M.D
Center for Medicare and Medicaid Services
Copy to Senate/Congress

RE: CMS-1506-P/CMS-1512-PN

Sir,

I would like to congratulate your office and the federal government on finally having the guts and conscience to do the right thing and plug the CMS "site fees" 1991 loophole in the law , which has fortunately enriched scores of my physician colleagues and driven the cost of endoscopic procedures through the roof. Many non-profit hospitals are nearing the verge of bankruptcy due to skimming of these paying cases by the ASC's to pocket the site fees.

I have always been a strong advocate for income parity between all physicians, and I feel we have a strong ethical and moral obligation to keep the heath care costs down, through cost-effective and safe delivery. Your bold and righteous move will appropriately move ASA class 1(>98%) endoscopic procedures into the office setting with the higher risk ones(class 2 and higher) appropriately being done in the out-patient hospital settings, like in the rest of the world.. The savings will be over a billion dollars to medicare and will eliminate unnecessary procedures and income disparities between physicians and will bring the costs down, and believe me, we gastroenterologists will still make a decent income in the office setting, unlike scores of my colleagues in other non-procedural cognitive medical fields. There is a lot of lard in the system which has to be trimmed and this is a bold and appropriate move, and my sincere congratulations again to the CMS, the President, Senate and the Congress.

Sincerely

PS: enclosed please find excerpts from a previous talk advocating office based endoscopy like in the rest of the world.

205 Bridge Street, Metuchen, NJ 08840 • Telephone: (732)205-9886 • Email: vasiboy@verizon.net

Office Endoscopy:
A Physician's Perspective

Srinivas Vasireddi, M.D., FACP
May 25, 2005

WHEN our GI colleagues SAY:

"It's Not About the Money...

..... IT'S ALWAYS ABOUT THE MONEY!!!!

GI Dollar Pyramid Exists

- Hospitalist GI's: $$
- Office based GI's: $$$$
- ASC GI's: $$$$$$

- Income disparity exists because of 1991 CMS 'loophole' Clubbing endo procedures with surgeries enabling OR/facility fees to be paid
- $1 Billion paid annually to all ASC's since 1991 (facility/tray fee)

"SHOW ME THE MONEY JERRY, SHOW ME THE MONEY!"

Rod Tidwell (Cuba Gooding Jr.) to his agent Jerry Maguire (Tom Cruise) in the move Jerry Maguire.

- "We have an obligation to society to hold down procedural costs, do the right thing for patients, and still have an acceptable level of income."

- Dr. Vasireddi on Office Endoscopy

The George Washington University
WASHINGTON DC
MEDICAL CENTER

SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES
CENTER FOR HEALTH SERVICES RESEARCH & POLICY

September 19, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Dear Dr. McClellan:

I am writing to request that the Centers for Medicare and Medicaid Services provide data regarding the current status of the Medicare Advantage program.

This request is that CMS provide data at the county level on the current enrollment of individual MA plans and on the current amount of Medicare payments per enrollee to individual MA plans.

This data was previously made publicly available by CMS though December 2005. This data is critical to the continuation of the analysis of the MA program that we have conducted for the past six years.

Overall, the request is for data on enrollment and payments to Medicare Advantage (MA) and Medicare Advantage-Prescription Drug (MA-PD) plans in 2006 in a manner and format similar to that available in 2005, with at least as much detail as 2005. The request also includes additional data that would be valuable in understanding the changes to the MA program that were implemented beginning in 2006.

In most cases, the requested data should be made available as an Excel spreadsheet. Data should not be rounded or small amounts deleted. Data should be consistent with other CMS-provided data on plans such as the Medicare Personal Plan Finder.

For all MA and MA-PD plans, the request includes:

1. Enrollment data at the county level, including actual enrollment by:

   A. Individual contract including contract number and firm name.

   B. Plan identifier number within each contract.

C. Contract type including: HMO, local PPO, regional PPO, PFFS, SNP, HMO/POS, local PSO, 1876 cost, national PACE, demonstration, and any other type of MA plan approved by CMS.

D. A SNP designation to identify all SNP plans.

E. MA and MA-PD plans.

2. Payment data at the county level, including the actual Medicare monthly payment to plans per enrollee by:

A. Individual contract including contract number and firm name.

B. Plan identifier number within each contract.

C. Contract type including: HMO, local PPO, regional PPO, PFFS, SNP, HMO/POS, local PSO, 1876 cost, national PACE, demonstration, and any other type of MA plan approved by CMS.

D. A SNP designation to identify all SNP plans.

E. Part A/B and Part D benefits

3. Plan average risk score for each MA and MA-PD plan by contract number and by plan identifier number within each contract.

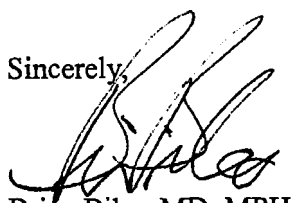
As noted earlier, this request is for data that was previously publicly released by CMS on an annual and monthly basis though December 2005. The request is for data on enrollment and payments to MA and MA-PD plans in a manner, format and detail similar to that available in 2005. The request includes some additional data for 2006 that would be valuable in understanding the changes to the MA program that were implemented beginning in 2006.

Since this data is critical to the continuation of the analysis of the MA program that we have conducted for the past six years, I look forward to an early provision of the requested enrollment and payment data.

If you or CMS staff has any questions regarding this request, please contact me at (202) 416-0066 or bbiles@gwu.edu.

Thank you very much.

Sincerely,



Brian Biles, MD, MPH
Professor

UnitedHealthcare®
A UnitedHealth Group Company

5901 Lincoln Drive Edina MN 55436

September 22, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: UnitedHealthcare comments submission regarding:
Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007; Proposed Rule. Federal Register / Vol. 71, No. 162 / Tuesday, August 22, 2006

Dear Sir or Madame:

Following your invitation UnitedHealthcare submits the attached comments on the referenced **Federal Register** publication regarding proposed revisions to payment policies under the physician fee schedule for calendar 2007.

The opportunity to participate in this forum is appreciated.

Sincerely,

Michael Ito, Vice President Network Management
UnitedHealthcare
5901 Lincoln Drive, MN012-S204
Edina, MN 55436
(952) 992-7384
Fax: (952) 992-4320

Enclosure: One original and two copies

CC: Robert Holman, Director, Pricing Schedule Management
Steve Affield

[Miscellaneous Coding Issues]: Assignment of RVUs to CPT Codes for Proton Beam Treatment Delivery Services

UnitedHealthcare comments
RVUs for these services should be established at the national level rather than carrier priced.

Deficit Reduction Act (DRA) Related Proposals [DRA ROPOSALS]: Maintain the multiple imaging payment reduction at its current 25 percent level and continue to examine appropriate payment levels.

UnitedHealthcare comments
While recognizing the decision to maintain the 25 percent reduction level, continued evaluation and examination of appropriate payment levels is encouraged because there is wide variation by diagnostic family in the resources required to perform certain contiguous imaging studies. This variation is acknowledged by the American College of Radiology (ACR).

Payment for Covered Outpatient Drugs and Biologicals [ASP Issues]: CMS seek comments on specific issues related to ASP drug price concessions and fees.

UnitedHealthcare comments
Currently, significant rebates are given to physicians for Aranesp bundled to purchases of Neupogen and Neulasta. The formulas incorporate targets for the total sales volume of all three medications, however the rebates are assigned to the cost of the Aranesp. Rebates should be proportionately distributed among the three medications based on drug cost.

The current practice allows the manufacturer to retain their high ASP for Neupogen and Nuelasta while owning 90 percent or higher share of this drug class. The rebates allow the manufacturer to offer artificially low rates for Aranesp against the competitor.

Coverage of [Bone Mass Measurement Tests]

UnitedHealthcare comments
Bone density screening should only be done when the physician will use it for medical decision making and the beneficiary will be treated with osteoporosis drugs if that diagnosis is confirmed on screening. Since lower bone density occurs even on low doses of corticosteroids, bone density screening should occur even at low dosages.

Public Consultation for Medicare Payment for New Outpatient [Clinical Diagnostic Lab Tests]

UnitedHealthcare comments
Carriers should be subject to detailed guidelines and instructions for establishing fees for new outpatient clinical diagnostic laboratory tests.

For each blood glucose test furnished to a resident of a SNF, the physician must certify that the test is medically necessary. Also, clarification that a physician's standing order is not sufficient to order routine blood glucose monitoring.

UnitedHealthcare comments
A standing order should not be sufficient to order routine blood glucose monitoring. However, there is little value in requiring an attestation of medical necessity for each blood sugar ordered provided that the tests are ordered real time and not as a standing order.

Clinical Diagnostic Laboratory Date of Service (DOS) for Stored Specimens: Subject to conditions, the date of service would be the date the specimen is obtained from storage.

UnitedHealthcare comments
The date of the test should be the date that the specimen is obtained, not the date that it is retrieved from storage. Test results change day to day even in medically stable patients. Test results obtained from a stored specimen on a date later retrieved from storage will not necessarily agree with the results on the date that the specimen was first obtained.

[Criteria for National Certifying Bodies-Advanced Practice Nurses]: Whether it would be appropriate to include the National Board on Certification of Hospice and Palliative Care Nurses under the list of recognized and approved national certifying bodies.

UnitedHealthcare comments
A national certifying body including hospice and palliative care nurses should be recognized. Hospice and palliative care for end of life services has a positive impact on both quality and cost for end of life care.

AACC
Improving healthcare through laboratory medicine

September 20, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8015
Baltimore, Maryland 21244-8015

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to comment on your proposed rule, published in the August 22, 2006 *Federal Register* notice, which outlines the Centers for Medicare and Medicaid Services (CMS) revisions to the physician fee schedule for 2007. Our comments follow:

Public Forums on New CPT Payment Amounts
CMS is proposing to formalize its current public consultation process in regards to new clinical laboratory tests. AACC supports the agency's plan, as outlined in the proposed rule. We are particularly pleased that CMS has agreed to publish the rationale for its initial and final payment decisions. We believe this is critical to the laboratory community understanding why a payment amount was selected, as well as providing a basis for a manufacturer, association or individual to appeal a decision.

New Gap-Fill Process
The agency proposes to modify the gap-fill process so that tests, which do not fit into an existing category, are paid at the national limitation amount at the start of the second year. In the first year, the new test would be paid at a rate determined by the local carrier. Although AACC supports this recommendation, we believe that there are flaws in the current gap-fill process that need to be addressed.

Currently, CMS forbids carriers from cross-walking a gap-filled code. We support this decision. However, we are concerned that some carriers may be cross-walking tests in spite of CMS's ban. For example, CPT code 83037 was included in the 2006 CPT Manual as a gap-filled code. As of July 1, 2006, reimbursement for 83037 ranges from $13.56—the existing cross-walk payment for 83036—to $23.49. It appears that some contractors may have cross-walked this code. We encourage CMS to investigate this matter and make sure that contractors follow the cross-walking prohibition.

VIRGIL H. GOODE, JR.
5TH DISTRICT, VIRGINIA

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Congress of the United States
House of Representatives
Washington, DC 20515–4605

September 14, 2006

Dr. Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
P.O. Box 8012
Baltimore, MD 21244

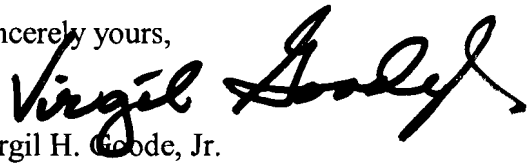
Dear Dr. McClellan:

I write expressing concern that the Centers for Medicare and Medicaid Services (CMS) proposed rule making adjustments in Medicare Part B practice expenses and relative work values (21 FR 37170, 6/29/2006) severely cuts Medicare anesthesia payment without precedent or justification. I ask that the agency consider reversing these cuts.

The proposed rule mandates 7-8 percent cuts in anesthesiology and nurse anesthetist reimbursement by 2007, and a 10 percent cut by 2010. With these cuts, the Medicare payment for an average anesthesia service would lie far below its level in 1991, adjusting for inflation. The proposed rule does not change specific anesthesia codes of values in any way that justifies such cuts. In fact, during CMS' previous work value review process that concluded as recently as December 2002, the agency adopted a modest increase in anesthesia work values. Further, Medicare today reimburses for anesthesia services at approximately 37 percent of market rates, while most other physician services are reimbursed at about 80 percent of the market level. The Medicare anesthesia cuts would be in addition to CMS' anticipated "sustainable growth rate" formula-driven cuts on all Part B effective January 1, 2007, unless Congress acts.

Many services whose relative values and practice expenses have been adjusted by the 5-year review proposed rule have been subject to extensive study and examination. However, the proposed rule indicates no such examination has been made on the effects that 10 percent anesthesia reimbursement cuts would have on peoples' access to healthcare services, and on other aspects of the healthcare system. I request that CMS review the impacts of this proposal and reconsider this rule.

Sincerely yours,



Virgil H. Goode, Jr.
70 East Court St., Suite 215
Rocky Mount, VA 24151

VHGJr/jna

Cc: Rebekah Carmel
149 Mill Creek Drive
Charlottesville, VA 22902

27

St Luke's HOSPITAL
ALLENTOWN CAMPUS

1736 Hamilton Street
Allentown, PA 18104
610-770-8300

August 30, 2006

To Whom it May Concern,

Our ED staff has reviewed the proposed changes to E&M coding guidelines. We have found the changes to be confusing and somewhat awkward.

We have recently implemented a new point system which we find more "user friendly" that what is being proposed.

Thank you for allowing us to send in our comments.

Faith Ring BSN

Faith Ring
Nurse Manager, Emergency Department
St. Luke's Hospital- Allentown Campus

Rick Neas

Rick Neas
Clinical Coordinator, Emergency Department
St. Luke's Hospital- Allentown Campus

Denise Stein RN, MSN, CCNP, CEN

Denise Stein
Clinical Nurse Specialist, Emergency Department
St. Luke's Hospital- Allentown Campus

Emergency Room Nursing Interventions/Other Charges

Patient Name _____
Account # _____
DOS _____

		Diagnostic Tests
	1628	ABG Collection (36600)
	2998	Breath Alcohol, Legal (82075)
	2997	Breath Alcohol, Medical (82075)
	1619	EKG 12-lead by nurse or tech (93005)
	1627	Glucometer reagent strip (82948)
	1626	Hemoccult, feces (82272)
	5004	Pulse ox spot check (94760)
	5005	Pulse ox monitoring, continuous (94762)
	1614	Updraft, Aerosol/Vapor Inhl Tx (94640)
	1625	Urinalysis, Dip w/o micros (81002) (Atown/Beth/ Miners)
		Lab SIM Department
	0075	ED Legal Urine Drug Screen (NIDA)
	3618	ED Pregnancy, Urine HCG testing (81025) (+) (-)
		Therapeutic Treatments
	1618	Cardioversion (92960)
	1620	CPR - initial multi-disciplinary response (92950)
	5002	Cardiac pacing external (92953)
	1654	IV Hydration, 1st Hour (90760)
	1655	IV Hydration, Ea Addl Hour (90761)
	1610	IV Drug Therapy, 1st Hour (90765)
	1611	IV Drug Therapy, Ea Addl Hour (90766)
	1656	IV Drug Therapy, Addl, Sequential (90767)
	1657	IV Drug Therapy, Concurrent(90768) **NA for MC/MA/SP**
	1621	IV Thrombolytic Coronary Infusion Therapy (92977)
	1612	Transfusion Therapy, Blood/Blood Products (36430)
	1633	Medication Injection, Tx/Dx, IM/Subcu (90772)
	1634	Medication Injection, Intra-arterial (90773)
	1635	Medication Injection, IV Push (90774)
	1658	Med Injection, IV Push, Ea Addl, Seqntl, New Rx (90775)
		Vaccine Administrations
	1630	TD Adult
	1631	DT Peds
	1632	Tetanus toxoid
	1629	Rabies IM
	1637	Rabies ID
	1638	Immune Globulin IM
	1639	Immune Globulin Rabies
	1640	Immune Globulin Rabies Ht Trtd
	1641	Immune Globulin Tetanus IM

Instructions for Choosing a Procedure Charge Code

If only one item is checked, then the corresponding charge code is entered.

If multiple Simple Procedures (1606) are checked off, all Simple Procedures included under Charge Code 1607

	1607	Multiple Simple procedures

If multiple Simple/Intermd Procedures (1606 & 1607) are checked off, all procedures included under Charge Code 1608

	1608	Simple &/or Multiple Intermediate procedures

If multiple Simple-Cmplx Procedures (1606-1608) are checked off, all procedures included under Charge Code 1609

	1609	Simple/Intermed &/or Multiple Complex procedures

If no Trauma Alert is Called and Critical Care Level is Checked, all Procedures Included Under Charge Code 1609

	1609	Medical Procedures, complex, multiple

If a Trauma Alert is Called all Procedures Included Under Charge Code 1255

	1255	Trauma Alert, team response (Bethlehem Facility Only)

If Multiple Items Are Checked In This Box, Please Refer to Specific Instructions for Choosing the Appropriate Charge.

		Medical Procedure Charges
	1606	Arthro,Aspir/Injection (20600, 20605, 20610)
	1606	Aspiration, Absc/Hema/Cyst/Bulla (10160)
	1606	Burn Care Simple, w/o ansth (16000, 16020)
	1607	Burn Care Intrmd, w/o ansth (16025, 16030)
	1607	Central line placement assist (36555, 36556)
	1606	Closed Treatment of Fracture, Simple
	1607	Closed Treatment of Fracture, Intermediate
	1608	Closed Treatment of Fracture, Complex
	1606	Closed Trmt Nursemaid Elbow w/Manipulation (24640)
	1606	Ear irrigation (69210)
	1606	Epistaxis Control, anterior (30901, 30903)
	1607	Epistaxis Control, posterior (30905)
	1606	Foley Catheter insertion (51702, 51703)
	1606	Foreign Body Rmvl, Subcu ,Simple (10120)
	1607	Foreign Body Rmvl, Subcu, Complicated (10121, 28190)
	1606	Foreign Body Rmvl, Eye w/wo Lamp(65205, 65220, 65222)
	1606	Gastric lavage/ GI decontamination (91105)
	1606	I&D Simple, single (10060)
	1607	I&D Complicated, multiple (10061)
	1608	I&D Ischiorectal/Perirectal Abscess (46040)
	1607	I&D Peritonsillar Abscess (42700)
	1606	Intraosseous infusion, needle placement (36680)
	1607	Intubation, endotracheal assist (31500)
	1606	Laceration repair assist, simple 1- 10 min
	1607	Laceration repair assist intermediate 10-20 min
	1608	Laceration repair assist, complex >20 min
	1606	Nails, (trimming, debridement, avulsion, evacuation)
	1607	Nails, Excision of nail and nail matrix (11750)
	1606	Paracentesis assist (49080)
	1607	Pericardiocentesis, Initial (33010)
	1609	Precipitous newborn delivery
	1606	Spinal Puncture, Lumbar, Diagnostic (62270)
	1606	Splinting & strapping (splints, immobilizers)
	1606	Thoracentesis assist (32000)
	1608	Thoracostomy, w/wo water seal (Chest tube 32020)
	1609	Thoracotomy assist (32110)
	1608	Tracheostomy assist (31603, 31605)
	1606	Trigger Point Injection (20550)
	1606	Tube Placement NG or OG w/fluoroscopy (43752)
	1608	Tube Placement Gastrostomy (43750)
	1606	Tube Change Gastrostomy (43760)
	1606	Wound Debridement, simple (skin/subcutaneous tissue)
	1607	Wound Debridement, intermed (skin/subcu/muscle)
	*	**Unlisted Procedure (Check off this item if the procedure performed is not listed above. Include a description in the space below. Enter all other charges & forward to the CDM dpt.)**

Revised 08/24/2006
R:\CDM\ER\08-24-06 SLHN 2 PG TSystm ER Points & Charges

Emergency Room Nursing Interventions/Level Charge

Patient Name _____

Account # _____

DOS _____

		Arrival			**Orthopedics**
	10	Ambulatory, wheelchair routine EMS or POV arrival		20	Crutch training and fitting
	50	Critical Transfer from other facility, mobile ICU or aircraft		15	ACE wraps, Slings, Aircasts
	10	Routine transfer in by EMS from other facility			
		Initial Nursing Assessment			**OB/GYN/GU**
	10	Triage - simple / re-check (ESI 4 & 5)		10	STD culturing
	15	Triage - complex (ESI 1, 2, & 3)		30	Newborn exam / APGAR scoring
	15	Nursing Assessment - simple (ESI 4 & 5)		80	Rape Exam
	20	Nursing Assessment - intermd/complex (ESI 1, 2, & 3)		20	Pelvic exam assist
	30	Nurse initiated protocols/directive/care paths		15	Fetal heart tone assessment
		Special Needs			
	10	Isolation and/or Latex allergy			**Point of Care**
	10	Special needs patients (sensory deficit/language)		20	Nurse monitoring pt, outside dept (CT, MRI, etc.)
	15	Patient with altered mentation		100	Conscious sedation
	50	Behavioral health		10	Glasgow coma scoring (neuro assessment)
	20	Case management/Crisis consult		15	Orthostatic vital signs
	30	Security alert		10	Specimen collection (stool, UA. Sputum/swabs)
	10	Seclusion / restraint monitoring, each 15 min		5	Visual acuity testing
		General Procedures			
	20	Bair hugger			**Discharge Instructions**
	20	SSE/ fleet enema		10	Special needs (transport/Rx needs)
	10	Dressing - simple		10	Simple discharge instructions(Rx, simple instructions sheet)
	15	Dressing - large or complex		15	Complex discharge instructions (detailed w/ follow-up)
	5	Eye exam/eye stain/ slit lamp exam			**Disposition**
	10	Eye irrigation/ morgan lens - per eye		50	DOA / expired in dept / coroner's case / post mortem care
	10	IV - simple saline lock		30	Involuntary admission / transfer
	15	IV - complex start (difficult, EJ scalp, foot, ped)		10	AMA / Elopement
	5	Medication - PO, rectal, topical, eye, ear G-tube (each)		10	Routine hospital admission
	5	O2 administration		20	Telemetry admission
	5	Phlebotomy (by nurse or lab)		30	ICU / operating room admission
	5	Ring Removal		40	Critical transfer to other facility (mobile, ICU, ALS, flight)
	20	Suctioning/ Irrigation		20	Routine transfer to other facility or nursing home
	10	Surgical Localized prep (Shave, scrub ethyl chloride)			**Critical Care**
	5	Suture/ staple removal - simple		15	Endotracheal suctioning, sterile, each time
	10	Suture / staple removal - complex, time consuming		30	Internal cardiac device care
	10	Wound cleansing or irrigation		30	Rapid infusion/fluid resuscitation
	5	X-ray - simple transport to radiology		45	Resuscitation response (non-CPR, in any room)
	10	X-ray - complex (CT, MRI, fluoro, nuclear med)		30	Specialty Alert (Stroke/MI)
		Monitoring		30	Trauma Consult, ED stat (Bethlehem Facility Only)
	20	Subsequent simple vital signs (excluding triage/discharge)		60	Trauma Alert, full team response (Bethlehem Facility Only)
	40	Continuous or complex, multi-system monitoring		30	Ventilator management
		Total Points Column 1			Total Points Column 2
		Total All Points			
1600		99281 = 0-20 points	1642		Triage only
1601		99282 = 21-55 points	1643		Prolonged Waiting Period (90+ minutes w/o treatment)
1602		99283 = 56-85 points			
1603		99284 = 86-115 points			
1604		99285 = >116 points (does not meet Critical Care criteria)			
1605		99291 = Critical Care (initial 30-74 minutes; direct pt care)			
1649		99292 = Critical Care (charge each additional 30 minutes)			

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THE CLEVELAND CLINIC FOUNDATION

August 28, 2006

Armin Schubert, M.D., M.B.A.
Chairman
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CMS-1321-P 3
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8015

Dear Sirs:

As a concerned anesthesiologist, I appreciate the opportunity to formally comment on the proposed rule published in the August 22 *Federal Register*. To prevent cuts in Medicare payments to physicians for 2007, the unfair SGR formula must be repealed and replaced.

The current SGR formula, based as it is on changes in the gross domestic product, has proven unworkable—essentially because changes in economic growth have little to do with the demand for medical services or the increasing cost of delivering them. If payments are cut in 2007, then Medicare physician payment rates will have fallen 20 percent below the government's conservative measure of inflation in medical practice costs in just six years.

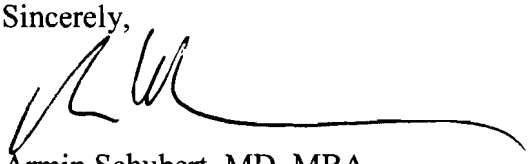
I request that you adopt the much more reasonable update mechanism previously recommended by MedPAC, in which the SGR would be replaced by a system that reflects increases in practice costs and other medical inflation variables. For 2007, MedPAC has recommended a Medicare physician payment update of 2.8%.

Evidence is growing that anesthesiologists and other physicians are seeking practice settings where the need to provide care to Medicare beneficiaries is at a minimum. With a nationwide shortage of anesthesia providers, this trend suggests a looming access crisis for many Medicare beneficiaries to surgical, pain medicine and critical care services.

A few years ago we saw a substantial decrease in anesthesiology trainees precipitated by the perception that there is no future in anesthesiology. The proposed cuts could well have a similar impact, which at the time meant operating room and pain clinic closures, as well as a large-scale disruption of teaching programs. I urge you to help prevent this from happening again!

Please replace the flawed SGR formula to avert further devastating cuts to the medical specialty of anesthesiology, and with that, a reduction in access to surgical health care.

Sincerely,



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29-1

Oasis Surgical

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Paul A. Carmichael, M.D.
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Fax: (209) 632-2062
2161 Colorado Avenue, Ste A
Turlock, California 95382

Office of The Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1321-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B

Dear Administrator,

I appreciate the occasion to relay my thoughts on the Center for Medicare and Medicaid Services' proposed rule, which was published in the Federal Register on August 22, 2006. I have some concerns regarding the proposed reduction of the RVUs of greater than 10 units when CPT code 19296 is performed in the office over the next few years as well as the proposed reduction of the conversion factor by 5.1%.

The anticipation of the proposed reduction of the conversion factor by 5.1% coupled with the reduction in RVUs will negatively affect the opportunity of the Physician to schedule Medicare beneficiaries in the office for this important procedure for women with breast cancer. The beneficiary may then be required to have services scheduled at the hospital, which provides greater cost to the Medicare system, as well as hinder quick access to the beneficiary who is being scheduled for catheter implantation for breast cancer radiation therapy. It is imperative that radiation therapy begin as soon as possible. It is important to keep the RVUs stable for this reason and not reduce them at the degree proposed. Many patients prefer scheduling this procedure in the Surgeon's office because of the ease of access. If payment is reduced this compromises the patient and places a financial burden on the system that may be unnecessary.

My recommendation is that CMS review this matter again and keep the current RVUs for this procedure or have a reduction that is significantly less than the proposed rate or reduce the conversion factor only, but not do both.

Once again, thank you for giving me a forum to express my concerns with this issue and the proposal at hand.

Oasis Surgical

Sincerely,

Paul Carmichael

Paul Carmichael, M.D.
Surgeon
2161 Colorado Ave, Suite A
Turlock, CA 95382

cc: Senator Barbara Boxer, CA (D)
Senator Diane Feinstein, CA (D)
Congresswoman Nancy Pelosi (D)

cc: Carolyn Mullen, Deputy Director,
Division of Practitioner Services

cc: American College of Surgeons
Mark A. Malangoni, MD, Chair, American College of Surgeons

30-0
35

Metropolitan
Anesthesia
Alliance

CMS-1321-P3
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8015

To Whom It May Concern:

As an anesthesiologist and a member of the American Society of Anesthesiologists (ASA), I am writing today to ask that you take every possible action to prevent cuts in Medicare payments to physicians for 2007 by **repealing and replacing** the unfair SGR formula.

Averting this crisis is more important now than ever because of new proposals released by CMS that would amount to a **10%** cut in Medicare payment to anesthesiologists over the next four years. This proposed cut, on top of potential SGR-related reductions, could irreparably damage my specialty.

The current SGR formula, based on changes in the gross domestic product, has proven unworkable—essentially because changes in economic growth have little to do with the demand for medical services or the increasing cost of delivering them. If payments are cut in 2007, then Medicare physician payment rates will have fallen **20 percent below** the government's conservative measure of inflation in medical practice costs in just six years.

ASA favors the update mechanism previously recommended by MedPAC, in which the SGR would be replaced by a system that reflects increases in practice costs and other medical inflation variables. For 2007, MedPAC has recommended a Medicare physician payment update of **2.8%**.

Evidence is growing that anesthesiologists and other physicians are seeking practice settings where the need to provide care to Medicare beneficiaries is at a minimum. With a nationwide shortage of anesthesia providers, this trend suggests a looming access crisis for many Medicare beneficiaries to surgical, pain medicine and critical care services.

Please work to fix the flawed SGR formula to avert further devastating cuts to the medical specialty of anesthesiology. Your constituents—my patients—are counting on you.

Sincerely,

Ben P Webber

Ben P. Webber, M.D.

BPW/gaj

1900 Exeter, Suite 210, Germantown, TN 38138
Phone: 901-818-2160 • Fax: 901-818-2163

31-0
16

Dr. Mark McClellan, MD PhD
Administrator
Centers for Medicare & Medicaid Services
P.O. Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I wish to express my serious concern that the Centers for Medicare & Medicaid Services (CMS) proposed rule making adjustments in Medicare Part B practice expenses and relative work values (71 FR 37170, 6/29/2006) severely cuts Medicare anesthesia payment without precedent or justification. I request the agency reverse these cuts.

The proposed rule mandates 7-8 percent cuts in anesthesiology and nurse anesthetist reimbursement by 2007, and a 10 percent cut by 2010. With these cuts, the Medicare payment for an average anesthesia service would lie far below its level in 1991, adjusting for inflation. The proposed rule does not change specific anesthesia codes or values in any way that justifies such cuts. In fact, during CMS' previous work value review process that concluded as recently as December 2002, the agency adopted a modest increase in anesthesia work values. Further, Medicare today reimburses for anesthesia services at approximately 37 percent of market rates, while most other physician services are reimbursed at about 80 percent of the market level. The Medicare anesthesia cuts would be in addition to CMS' anticipated "sustainable growth rate" formula-driven cuts on all Part B services effective January 1, 2007, unless Congress acts.

Last, hundreds of services whose relative values and practice expenses have been adjusted by the 5-year review proposed rule have been subject to extensive study and examination. However, the proposed rule indicates no such examination has been made on the effects that 10 percent anesthesia reimbursement cuts would have on peoples' access to healthcare services, and on other aspects of the healthcare system.

For these reasons, I request the agency suspend its proposal to impose such cuts in Medicare anesthesia payment, review the potential impacts of its proposal, and recommend a more feasible and less harmful alternative.

Sincerely,

Patricia M Violi

Patricia M. Violi, CRNA

32-0
6

September 1, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1321-P
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-1321-P -- Changes to the Physician Fee Schedule for Calendar Year 2007; -- Request for Office Practice Expense RVUs for Arthroscopy Procedures

Dear Dr. McClellan:

In response to the above referenced proposed rule which recommends payment policies under the Medicare physician fee schedule for calendar year 2007, [1] I am writing to ask that you establish office-based practice expenses for orthopedic arthroscopy procedures described by CPT codes 29870, 29805, 29839, 29840, 29860. Making this important revision to the Medicare physician fee schedule would allow orthopaedic physicians such as myself to improve the diagnosis and treatment of joint problems afflicting many Medicare patients by ensuring that we can continue to furnish these services. Thus, I encourage CMS to assign non-facility (office) practice expense relative value units to CPT codes 29870, 29805, 29839, 29840, 29860 in the final 2007 physician fee schedule rule.

As you may be aware, significant refinements in the arthroscopes and instruments used for arthroscopy procedures in the past few years have made it more practical for doctors to furnish arthroscopy procedures in the office setting. Using smaller arthroscopes, we are better able to assess, on a more immediate basis, the etiology of a patient's complaints. Often, this allows us to forego ordering more expensive and time consuming MRI scans. In addition, with development of better instrumentation and surgical techniques, many conditions now can even be treated arthroscopically, resulting in much easier patient recovery than open surgery.

Unfortunately, under the current physician fee schedule physicians are not adequately reimbursed for the significant practice expenses associated with providing arthroscopies in the

1 Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B, 71 Fed. Reg. 48981 (August 22, 2006)

2050 Kenny Road, Columbus, Ohio 43221
(614) 293-3600

office setting. While the supplies and devices used for arthroscopy procedures are estimated to cost nearly $1,000 per procedure, the CPT codes associated with providing arthroscopies in the physician office do not include a practice expense component. As a result, doctors often can not afford to provide arthroscopy services in the more efficient office setting.

To avoid jeopardizing patient access to this exciting technology, I respectfully request that CMS add **non-facility (office) practice expense relative value units (PE RVUs) to cover physician office expenses for CPT codes 29870, 29805, 29830, 29840, 29900 arthroscopy procedures.** The American Association of Orthopaedic Surgeons (AAOS) requested that CMS assign non-facility PE RVUs to these codes as long ago as 1998.

CMS can easily correct the payment inequity facing doctors who wish to provide arthroscopy procedures in the office setting by establishing non-facility PE RVUs which take into account the costs of the devices and supplies used to provide in-office arthroscopy services falling under CPT codes 29870, 29805, 29830, 29840, and 29900. Appropriate payment under the Medicare physician fee schedule will allow physicians to more expeditiously manage our patients' conditions and preserve patient access to vital, more efficient, and cost effective in-office arthroscopy procedures.

Thank you for your consideration of this important matter.

Sincerely,

Christopher C. Kaeding, M.D.
Judson Wilson Professor and Interim Chairman
OSU Department of Orthopaedics
Head Team Physician, OSU Department of Athletics
Medical Director, OSU Sports Medicine Center

cc: Carolyn Mullen
Gail Daubert

33-O
43

Original plus Two Copies via Federal Express

October 4, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8010

RE: CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for CY 2007 and Other Changes to Payment Under Part B, Specifically **"Provisions Regarding Resource-Based Practice Expense (PE) RVU Proposals for CY 2007."**

Dear Dr. McClellan:

As a obstetrician/gynecologist practicing in Phoenix, Arizona, I am writing in response to the publication of CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for CY 2007 and Other Changes to Payment Under Part B, specifically "Provisions Regarding Resource-Based Practice Expense (PE) RVU Proposals for CY 2007." I am particularly concerned with the negative effect of these changes on the practice expense RVUs for CPT code 58565 – Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants, by CY 2010.

I understand that major changes to the PE methodology for CY 2007 were discussed in the June 29, 2006 proposed notice. However, I am concerned that the specific, proposed practice expense RVUs published in this regulation for CPT codes 58565 by the end of the transition period in CY 2010 will negatively impact access to this procedure when performed in a physician's office.

I am concerned that CMS' proposed method uses budget neutrality adjustors in three separate steps. I cannot continue to absorb these under-valuations, especially as my practice faces 37% in Medicare payment cuts over the next nine years, as projected by the Medicare Trustees. For example, the impact of the budget neutrality adjuster on the direct expenses means over $350 of the direct costs for CPT code 58565 are not included as part of the practice expense valuations for this code under the new methodology. Given that many private insurance companies and Medicaid programs use the Medicare physician fee schedule to set their payment rates, the impact of CMS not accounting for all the costs of the procedure are magnified with each additional payer.

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4545 East Chandler Blvd, Suite 208 Phoenix, Arizona 85048 Tel 480.961.2330 Fax 480.961.2332
1187 E. Cottonwood Lane, Suite B Casa Grande, Arizona 85222 Tel 520.836.1000 Fax 520.836.6515
www.newhorizonswomenscare.com

Also, I understand that as CMS calculates the service level allocators for the indirect PEs, which happen to be the direct PE RVUs and the work RVUs, they are using direct PE RVUs or work RVUs that have been adjusted for budget neutrality. Indirect costs for a service need to allocate using all of the costs associated with the inputs for a service.

It is important that Medicare payment levels are appropriate such that access to permanent birth control that is non-incisional does not become constrained for women of child-bearing age. In my practice, I have treated many women with the Essure® micro-insert system and their outcomes have been excellent, with less risk and complications versus an open, surgical tubal ligation procedure. Therefore, CMS needs to be sure that the direct costs for this procedure used in its calculations are accurate and totally accounted for in the PE RVUs. It would be unfortunate if access to this non-incisional, permanent birth control for women with Medicaid or commercial insurance was no longer a viable option for me to offer my patients because of the practice expense formula used to calculate Medicare payments starting in 2007 and beyond.

Please do not hesitate to contact me at 480-895-9555 of help with regard to providing additional information or answering any questions you or your staff may have.

Sincerely,

Robert J. Marotz, DO, FACOG

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Lincoln
SPECIALTY CARE CENTER

A Leading Provider of Sub-Acute Rehabilitation, Dialysis, Complex Medical, IV Therapy, Long Term Care, and Comprehensive Personal Care

September 21, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1321–P
P.O. Box 8015
Baltimore, MD 21244–8015.

RE: Federal Register, August 22, 2006, Proposed Rules for Blood Glucose Testing

Dear Sir:

I believe the proposed rule for blood glucose testing does not meet the spirit and intent of the Medicare program. The proposed regulation is unduly restrictive and contrary to the Act, the governing regulations, inconsistent with Medicare's National Coverage Decision (PM-AB-02-110) and contrary to standards of medical practice.

The NCD (PM-AB-02-110) recognizes that blood glucose testing is necessary for patients with diabetes and other defined medical conditions. The NCD specifically states that testing "using a device approved for home monitoring or by using a laboratory assay system using serum or plasma" is covered. It is also clear that this coverage determination encourages use of devices for home monitoring. The NCD goes on to say that the "convenience of the meter or stick color method allows a patient to have access to blood glucose values in less than a minute or so and has become a standard of care for control of blood glucose, even in the inpatient setting (underline added). The NCD does not place any specific limitations on the frequency of testing. In fact the NCD simply states that "frequent home blood glucose testing by diabetic patients should be encouraged."

CFR 410.32(a) requires that in order for a diagnostic test to be considered reasonable and necessary it must be ordered by a physician and the ordering physician must use the result in the management of the beneficiary's specific medical problem. In the case of an SNF a physician orders blood glucose testing usually based on a sliding scale for a month at a time. These are explicit instructions to the attending RN to provide X amount of insulin for Y reading with instructions for immediate physician contact on outlier readings (unreasonably high or low readings). The physician reviews the results of these tests on his monthly visit, considering changes in patient's diet, change of medications that may affect glucose levels, physical or cognitive issues etc. The physician either modifies or renews his testing and insulin orders as a result of his review of the test results achieved. Thus it is quite clear that the physician utilizes these results in the patient's plan of care. It is ludicrous to expect a physician to be contacted several times a day to transmit test results and it is certainly contrary to current standards of medical practice.

CMS Pub 100-8 Chapter 13.5.1 states that in pertinent part that a service is considered reasonable and necessary when "furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition", is "ordered and furnished by qualified personnel" and "meets, but does not exceed, the patient's medical need." In an SNF the accepted standard of medical practice is for the physician to order these glucose tests to treat the patient. Orders are executed by an RN qualified to administer the test, read the results and act on the physician's order to dispense insulin. These procedures are the "accepted standard of medical practice" today. For this proposed regulation to summarily state that a physician's standing order will not be acceptable as reasonable and necessary clearly violates Pub 100-8 Chapter 13.5.1.

collaboratively with the clinical laboratory community on these issues.

b. Blood Glucose Monitoring in SNFs

In response to inquiries regarding our policy on blood glucose monitoring in SNFs, we are taking this opportunity to restate our long-standing policy on coverage of blood glucose monitoring services and to propose to codify physician certification requirements for blood glucose monitoring in SNFs.

Generally, section 1862(a)(1)(A) of the Act requires that a service be reasonable and necessary for diagnosis and treatment in order to be eligible for coverage by Medicare. Our regulations at § 410.32(a) already require that, for any diagnostic test, including a clinical diagnostic laboratory test, to be considered reasonable and necessary, it must be both ordered by the physician and the ordering physician must use the result in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.

In the context of blood glucose monitoring, we most recently stated this policy in Transmittal AB–00–108, "Glucose Monitoring", which is available on our Web site at *http://www.cms.hhs.gov/transmittals/downloads/ab00108.pdf*. This interpretation of § 410.32 is also the basis for our policy in Chapter 7 of the Medicare Claims Processing Manual ("Skilled Nursing Facility Part B Billing" available on our Web site at *http://www.cms.hhs.gov/manuals/downloads/clm104c07.pdf*.)

In addition, section 1835(a)(2)(B) of the Act provides that, in the case of certain "medical and other health services" (including clinical diagnostic laboratory services), payment may be made for Part B services that are furnished by a provider of services only if a physician certifies—and recertifies where those services are furnished over a period of time, with such frequency, and accompanied by such supporting material, as may be provided by regulation—that those services were medically necessary. The regulations currently implementing this provision at § 424.24 do not specifically address the issue of blood glucose monitoring in SNFs. Therefore, we are proposing to amend § 424.24 to provide that, for each blood glucose test furnished to a resident of a SNF, the physician must certify that the test is medically necessary. We are also proposing to amend § 424.24 to clarify that a physician's standing order is not sufficient to order routine blood glucose monitoring.

c. Other Lab Issues—Proposed Clinical Diagnostic Laboratory Date of Service (DOS) for Stored Specimens

We are proposing to add a new § 414.410 to address concerns that have been raised regarding the date of service of a clinical diagnostic laboratory test that use a stored (or "archived") specimen. In the final rule of coverage and administrative policies for clinical diagnostic laboratory services that we published on November 23, 2001 (66 FR 58792), we adopted a policy under which the date of service for clinical diagnostic laboratory services generally is the date the specimen is collected. For laboratory tests that use an archived specimen, however, the date of service is the date the specimen was obtained from the storage. In 2002, we issued Program Memorandum AB–02–134 which permitted contractors discretion in making determinations regarding the length of time a specimen must be stored to be considered archived. In response to comments requesting that we issue a national standard to clarify when a stored specimen can be considered "archived," in the Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services final notice, published in the **Federal Register** on February 25, 2005 (70 FR 9355), we defined an "archived" specimen as a specimen that is stored for more than 30 calendar days before testing. The date of service for these archived specimens is the date the specimen was obtained from storage. Specimens stored 30 days or less have a date of service of the date the specimen was collected. The February 25, 2005 final notice also clarified that the date of service for tests when the collection spanned more than two calendar days is the date the collection ended. Instructions that implemented these policies were added to Chapter 16, section 40.6 of the Medicare Claims Processing Manual (Pub. 100–04) with the issuance of Transmittal 800 (CR 4156), on December 30, 2005.

Recently, we have received correspondence that expressed concern that our policies have created some unintended consequences, especially in situations in which a specimen is taken in a hospital setting, but then later used for a test after the patient has left the hospital. Under the current manual instructions, if the specimen used for a test ordered subsequent to the beneficiary's discharge is obtained less than 31 calendar days following the date the specimen was collected, the date of service of the test is the date of collection. The date of service of a test may affect payment because, if the date of service falls during an inpatient stay or on a day on which the beneficiary had an outpatient procedure, payment for the laboratory test usually is bundled with the hospital service. To address these concerns, we are proposing to change our current policy so that the date of service would be the date the specimen is obtained from storage, even if the specimen is obtained less than 31 days from the date it was collected, without violating the unbundling rules as long as the following conditions are met:

- The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital.
- The test could not reasonably have been ordered while the patient was hospitalized.
- The procedure performed while the beneficiary is a patient of the hospital is for purposes other than collection of the specimen needed for the test.
- The test is reasonable and medically necessary.

These conditions are consistent with the guidance in Chapter 16, sec 40.3 of the Claims Processing Manual, which states that "When the hospital obtains laboratory tests for outpatients under arrangements with clinical laboratories or other hospital laboratories, only the hospital can bill for the arranged services."

In addition, Chapter 3 of the Program Integrity Manual contains instructions for additional documentation if further development of laboratory claims for pre-or postpay are required. Although we believe these changes will help to maintain beneficiary access to care, we are concerned about the potential for these policy changes creating inappropriate incentives in the development of technology and the implications for the unbundling of services. We solicit comment on the proposed changes and these concerns.

O. Proposal to Establish Criteria for National Certifying Bodies That Certify Advanced Practice Nurses

[If you choose to comment on issues in this section, please include the caption "Criteria for National Certifying Bodies-Advanced Practice Nurses" at the beginning of your comments.]

Federal regulatory qualifications for nurse practitioners (NPs) at 42 CFR 410.75 require that an individual be certified as an NP by a recognized national certifying body that has established standards for NPs. Similarly, Federal regulatory qualifications for clinical nurse specialists (CNSs) at 42

RITA ROVER, MA, MS, RD **MEDICAL NUTRITION THERAPY**

168 LAUREL AVENUE
NORTHPORT, NY 11768
Phone: 631-261-8386

September 27, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Provisions—Medical Nutrition Therapy Services (CPT Codes 97802-4)

I join in the attached comments of Midtown Nutrition Care, especially paragraph 35. A Medicare medical nutrition therapy visit "for the purpose of disease management" with a physician who is also a dietitian would encompass the work of an evaluation and management visit; otherwise the text following CPT 97802-4 would be meaningless: "For medical nutrition therapy assessment and/or intervention performed by a physician, see Evaluation and Management or Preventive Medicine service codes."

Although not statutorily required, it appears that a Medicare medical nutrition therapy visit "for the purpose of disease management" with a dietitian who is not a physician would also encompass the work of an evaluation and management visit, as described in detail in paragraph 37 of Midtown Nutrition Care's comments.

I have been a private practice dietitian for 19 years in Long Island, New York, and have seen over 5,000 patients in that time, many with diabetes or kidney disease. Because Medicare fees are less than half of what I typically receive from commercial health plans, and well below my break-even, I cannot afford to participate in Medicare, but if an appropriate payment structure were established I would become a Medicare provider.

Although I realize that private market behavior is not controlling, I would also like to bring to your attention the situation that existed prior to the adoption of CPT 97802-4; that is, that private carriers had us report our services as evaluation and management services. Some paid for these services by applying a discount, similar to the 15% Medicare statutory discount, and some paid in full, without discount.

Sincerely,

Rita Rover, RD

MIDTOWN NUTRITION CARE
119 WEST 57TH STREET
NEW YORK, NY 10019
(212) 333-4243

September 11, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: August 22, 2006 Proposed Rule, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Issue Identifier: PROVISIONS—MEDICAL NUTRITION THERAPY SERVICES, CPT 97802-4, G0270-1 (II. Provisions of the Proposed Rule, A. Resource-Based Practice Expenses (PE) RVU Proposals for CY 2007, 3. Medical Nutrition Therapy Services, 71 FR 48987)

Dear Sir or Madam:

Midtown Nutrition Care (Midtown), a single specialty nutrition group practice with 7 registered dietitians, respectfully submits the following comments.

Table of Contents

Attachment B—July 2000 HCPAC Recommendations and August 1, 2000 transmittal memo (4 pages)

Attachment C—January 3, 2006 letter from ADA to CMS (4 pages)

Attachment D—March 24, 2006 letter from ADA to CMS (3 pages)

Attachment E—Section 105 of BIPA and Statement of the Manager For Section 105 (2 Pages)

Attachment F—March 2000 RUC Update Survey (24 pages)

Summary of Points

The work RVUs for the three individual 15-minute medical nutrition therapy codes CPT 97802, 97803 and G0270 should all be the same. The work RVUs for the medical nutrition therapy codes should be based on the 15-minute consultation code CPT 99241 rather than on the 15-minute and 30-minute physical therapy codes CPT 97110 and 97150.

Inadequate Reimbursement = Lack of Access

1. Last year, in the Calendar Year 2006 Proposed Rule, CMS proposed eliminating the nonphysician work pool, formerly known as the zero-work pool, and stated: "We recognize that there are still some outstanding issues that need further consideration, as well as input from the medical community. For example, although we believe that the elimination of the nonphysician work pool would be, on the whole, a positive step, some practitioner services, such as audiology and medical nutrition therapy, would be significantly impacted by the proposed change.... We, therefore, welcome all comments on these proposed changes..." (70 FR 45777, second column).

2. As members of the medical community Midtown submitted comments dated September 22, 2005 from our group and from the original sponsor of the medical nutrition therapy benefit bills, Congressman Jose Serrano. Comments were also submitted by our professional society, the American Dietetic Association (ADA).

3. These comments showed that even without further reduction current reimbursement rates are inadequate, and urged that appropriate work RVUs be assigned to the Medical Nutrition Therapy codes in order to give effect to the intention of Congress to provide adequate payment for these services, so that access to these services would become generally available to the Medicare beneficiaries entitled thereto, namely, patients with diabetes or renal disease.

4. That the access to care envisioned by Congress does not exist is shown by the following three items. First, prior to passage of the medical nutrition therapy benefit the Congressional Budget Office estimated the annual cost of medical nutrition therapy services to be 60 million dollars, but only a few million dollars have been spent annually since the benefit became available in 2002. Second, this represents visits by only about 250,000 beneficiaries out of an estimated 8 million beneficiaries with diabetes or renal disease. Third, only about 10% of dietitians (7,000 out of 65,000 nationwide) have become Medicare providers, compared with over 90% of physicians. For a discussion of these three items, see Journal of the American Dietetic Association, June 2005, p. 990 and p. 995 (footnote references).

5. In our case, as our September 22, 2005 comment showed, Medicare pays less than half the fees paid by insurers in our area that have independently valued these codes. Medicare's fees are well below our break-even level. Therefore we cannot afford to treat Medicare patients and none of us has become a Medicare provider. We turn away a couple of Medicare patients every day and most of these patients are unable to obtain medical nutrition therapy services because virtually none of the dietitians in our area accept Medicare.

6. In the Calendar Year 2006 Physician Fee Schedule Final Rule no decision was made regarding medical nutrition therapy work RVUs; that decision was put off to this year: "Because we are maintaining the NPWP for 2006, we are deferring our decision regarding work RVUs for audiology, speech language pathology and medical nutrition pending further discussions with the specialties." (70 FR 70134, first column).

7. In the Calendar Year 2007 Proposed Rule CMS stated it would establish work RVUs and remove clinical labor time in the practice expense direct input database: "Because we propose to add the work RVUs to these services, the MNT clinical labor time in the direct input database would be removed with the adoption of this proposal." (71 FR 48987, third column).

8. The assignment of work RVUs coupled with the removal of clinical labor time from the practice expense direct input database would raise the fully implemented non-facility total RVU of the 15-minute new patient visit code CPT 97802 from **0.48** to **0.58**, leave the 15-minute established patient visit codes CPT 97803 and G0270 total RVU of **0.48** unchanged, and raise the 30-minute group codes CPT 97804 and G0271 total RVU from **0.19** to **0.32**. (70 FR 70457, 70462; 71 FR 49231, 49235).

9. Given the approximately 10% adjustment required to preserve budget neutrality (71 FR 37241, first-second columns), this means that the new patient visit code would pay about 5% more than currently, the established patient visit codes would pay about 5% less than currently, and the group codes would pay about 50% more than currently. Although the group fees would be adequate, neither our practice nor the practices or employment settings of other dietitians have many group visits compared to individual visits. Therefore if these RVUs are carried over to the Final Rule our practice and other dietitians will still be unable to afford to treat Medicare patients, allowing the lack of access to care to continue.

The Work RVUs Should Be the Same for the Individual Codes

10. The proposed work RVUs are those recommended on an interim basis by HCPAC in July 2000, transmitted to CMS by memo dated August 1, 2000, a copy of which is attached as Attachment B.

11. These recommendations were based on a RUC survey conducted in March 2000 (Attachment F) for seven proposed, but never adopted, Medical Nutrition Therapy codes, 3 initial visit codes, 3 follow-up visit codes and 1 group visit code, modeled after the office visit code series CPT 99201-99205, 99211-99215.

12. Unlike the time-based codes that were adopted, these 7 codes were based on level-of-complexity. Thus the survey data showed that follow-up visits would have lower RVUs because at the same level of complexity the follow-up visit will take less time than the initial visit.

13. But because a shorter visit will take less time, it will also have fewer 15-minute increments. Therefore there is no need to value the 15-minute follow-up visit increment less than the 15-minute initial visit increment. In fact doing so amounts to a double reduction of the fee, first for fewer 15-minute increments, and then a lower RVU for the each increment.

14. HCPAC stated at the bottom of the first page of the July 2000 Recommendations (Attachment B): "This recommendation maintains the relativity of CPT code 97803 and 97804 as presented by the survey data and original work relative value recommendations from the American Dietetic Association." Somehow HCPAC overlooked the fact that the survey data was based on the never adopted level-of-complexity codes, while the adopted codes were purely time-based codes.

15. Using the survey data, HCPAC valued the15-minute follow-up increment 73% less than the 15-minute initial visit increment, estimating that the typical CPT 97802 visit would take 75 minutes (pre, intra and post visit time), while the typical CPT 97803 visit would take 55 minutes (pre, intra and post visit time), or 73% less time ($55 \div 75 = 73\%$).

16. All of the CPT codes that are time-based, other than the Medical Nutrition Therapy codes, use the same code for their initial and follow-up visits, so their initial and follow-up time increments will pay the same. See, for example, the preventive medicine counseling codes CPT 99401-99412 and the psychiatric therapeutic psychotherapy codes CPT 90804-90829.

17. In fact, were it not for CMS's need to use CPT 97803 and G0270 to keep track of the number of follow-up visits and change-of-diagnosis follow-up visits, it would need only one code for all individual visits. But just because CMS needs to use two additional follow-up visit codes is no reason to value the 15-minute increments of those codes less than the 15-minute increment of the initial visit code.

18. CMS recognized that initial and follow-up time-based medical nutrition therapy codes should be valued the same when CMS valued the later-created group change-of-diagnosis 30-minute follow-up code G0271 the same as the CPT 30-minute group code CPT 97804. (70 FR 70457, 70462).

19. But more to the point, the question of whether the individual 15-minute codes would be valued the same or differently was an issue once before, in the preparation of the Calendar Year 2002 Physician Fee Schedule. The Calendar Year 2002 Proposed Rule had proposed a lesser value for the 15-minute follow-up increments. The issue was fully discussed in the Proposed Rule, in comments thereto, and in the Final Rule, which concluded that all of the time-based Medical Nutrition Therapy codes should have the same hourly rate: "A commenter representing dietitians asked us to review the relativity of payment across the three medical nutrition CPT codes. The commenter indicated that payment for CPT code 97803 was set at 72.9 percent of proposed RVUs for CPT 97802 and 97804 was set at 31 percent of CPT code 97802. The commenter argues that, because reassessments are shorter than initial assessments, the proposed RVUs are actually discounted twice (that is, less payment per 15 minutes of time as well as less total time). They believe the value of CPT codes 97802 and 97803 should be identical.... We have reviewed the payments for CPT codes 97802 and 97803 and agree with the commenter that these two codes should have the same values. The essential difference between an initial and follow up medical nutrition therapy service is the time spent performing the service. Initial visits will be longer than follow-up visits and will likely involve Medicare payment for more increments of service. We will pay less for follow up visits because they will typically involve fewer 15-minute increments of time than an initial visit. The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the proposed rate for CPT code 97802. We have also changed the payment rate for CPT code 97804 assuming that the code will normally be billed for 4 to 6 patients with the average of 5. Using the revised values, the payment rate for group medical nutrition therapy would approximate the hourly rate paid for other medical nutrition therapy services." (68 FR 55280, first-second columns).

20. That reasoning was sound and remains sound and should continue to be followed, rather than create a **0.08** less work RVU for CPT code 97803 and G0270 (0.45 – 0.37 = 0.08). (71 FR 49231, 49235).

Use the Work RVU of the 15-Mintue Consultation Code

21. CMS may accept or reject HCPAC work RVU recommendations. (71 FR 37173, third column). In this instance we submit that CMS should reject the July 2000 HCPAC interim recommendations, which base the medical nutrition therapy work RVUs on the 15-minute and 30-minute physical therapy codes CPT 97110 and 97150, and instead base the work RVUs on the 15-mnute consultation code CPT 99241.

22. The July 2000 HCPAC interim recommendations regarding the new Medical Nutrition Therapy codes were unusual in that they were initially submitted for the Calendar Year 2001 Physician Fee Schedule before CMS had the statutory authority to

value these codes for Medicare payment (71 FR 48987, first-second columns), because the law that created the medical nutrition therapy benefit was not enacted until later, in December 2000, and created the benefit for these services starting in the Calendar Year 2002. See PL 106-544, Appendix F, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Section 105, Coverage of Medical Nutrition Therapy Services for Beneficiaries With Diabetes or a Renal Disease, and the published legislative history set forth in the Statement of the Manager For Section 105, both attached as Attachment E.

23. When HCPAC was making its interim work recommendations, HCPAC did not know what the statute would eventually contain. Therefore HCPAC looked solely to the text of the Medical Nutrition Therapy codes CPT 97802-4 which describe medical nutrition therapy services in bare-bones terms as "assessment [or re-assessment] and intervention, individual [or group], face-to-face with the patient, each 15 [or 30] minutes." On the other hand the statute defines medical nutrition therapy services much more comprehensively as "diagnostic, therapy and counseling services for the purpose of disease management", Section 105(b) of BIPA, 42 U.S.C. 1395x(vv)(1), and provides that payment of 85% to dietitians be determined "for the same services if furnished by a physician." Section 105(c)(2) of BIPA, 42 U.S.C. 1395l(a)(1)(T).

24. Since HCPAC was recommending work RVUs when it was not even cognizant of what the statutory definition would be, HCPAC was able to compare the15- and 30-minute individual and group medical nutrition therapy codes to "other modality or treatment codes" (middle of the first page of the July 2000 Recommendations, Attachment B), in this case the 15- and 30-minute individual and group physical therapy codes CPT 97110 and 97150.

25. These treatment codes are poor comparisons given the (now known) statutory definition of medical nutrition therapy in Section 105(b), 42 U.S.C. 1395x(vv)(1), which includes diagnosis and counseling as well as therapy.

26. In the 2002 Physician Fee Schedule Proposed and Final Rules CMS had compared medical nutrition therapy services to the 15-minute preventive medicine counseling code CPT 99401: "Commenters...believe that medical nutrition therapy payment should not be based on comparison to a preventive medicine code (CPT code 99401) in the zero-work pool methodology. The commenters indicated that preventive medicine services omit the problem-oriented components of the comprehensive history, as well as other essential assessment points, such as the patient's chief complaint and history of present illness." (66 FR 55279, third column-55280, first column).

27. In prior submissions to CMS Midtown had also proposed that the work RVUs for the Medical Nutrition Therapy codes could be based on the 15-minute preventive medicine counseling code CPT 99401. However Section 105(b), 42 U.S.C. 1395x(vv)(1), defines medical nutrition therapy services as services provided "for the purpose of disease management", that is, for patients with established illness. So a crosswalk to CPT 99401 would not be appropriate, because the CPT text prior to Sections 99401-99429 states (third paragraph of text): "These codes [preventive medicine counseling codes] are not to

be used to report counseling and risk factor reduction interventions provided to patients with symptoms or established illness. For counseling individual patients with symptoms or established illness, use the appropriate office, hospital or consultation or other evaluation and management codes [emphasis supplied]."

28. A more appropriate crosswalk, according to the text quoted above, would be to the work RVU of an office visit or consultation code.

29. Section 105(b), 42 U.S.C. 1395x(vv)(1), provides that a medical nutrition therapy visit be "pursuant to a referral by a physician", to whom a report is sent post-visit. Therefore the visit could be considered a consultation. If so, the work RVU could be that of the 15-minute consultation code CPT 99241, which has a work RVU of **0.64** as of the 2006 Physician Fee Schedule, and the same **0.64** is proposed for the 2007 Physician Fee Schedule. (71 FR 37218, second-third columns; 71 FR 49232).

30. The medical nutrition therapy visit could also be considered an office visit. If so, the work RVU could be that of the 15-minute established patient office visit code CPT 99213, which has a work RVU of **0.67** as of the 2006 Physician Fee Schedule (70 FR 70458) and a proposed work RVU of **0.92** for the 2007 Physician Fee Schedule. (71 FR 37218, second-third columns; 71 FR 49232).

31. CMS could use either the work RVU of CPT 99241 or the work RVU of CPT 99213 as the work RVU for the 15-minute individual Medical Nutrition Therapy codes CPT 97802, 97803 and G0270; and as the basis for the work RVU for the 30-minute group codes CPT 97804 and G0271 in the same manner as was done in the Calendar Year 2002 Physician Fee Schedule Final Rule; that is, by multiplying the CPT 97802 RVU by 2 then dividing by 5. (66 FR 55281, first column).

32. The Calendar Year 2002 Physician Fee Schedule Final Rule, however, had rejected a valuation crosswalk to E/M codes, making the following analysis for the first time in the Final Rule, though not in the Proposed Rule (so no comments may have been received questioning such analysis): "We do not believe that it is appropriate to compare medical nutrition therapy provided by a registered dietitian to an E/M service provided by a physician. Registered dietitians do not take medical histories, they are not trained and do not perform physical examinations, nor do they make medical decisions. Furthermore, when physicians use an E/M code, they typically have also performed a medical history, physical examination, and engaged in medical decision making as part of that service. If such an individual performed a service that met the requirements of an E/M service, then it would be appropriate for him or her to report an E/M service [emphasis supplied]." (66 FR 55278, third column).

33. This analysis misread the statute, which specifies that the amount paid be determined by comparing medical nutrition therapy services provided by a physician, not by comparing medical nutrition therapy services provided by a registered dietitian. Section 105(c)(2), 42 U.S.C. 1395l(a)(1)(T), states "the amount paid shall be...85 percent of the amount determined ... for the same services if furnished [i.e., provided] by a physician".

(See the third sentence of the Statement of the Manager For Section 105, Attachment E, "... if such services were provided by a physician [emphasis supplied].")

34. CMS has acknowledged that: "Physicians will occasionally meet the statutory qualifications to be considered a registered dietitian or nutrition professional who can bill Medicare for medical nutrition therapy services. (66 FR 55279, second column).

35. If a physician who is also a dietitian has a medical nutrition therapy visit "for the purpose of disease management" the physician will perform the 3 key components, taking a medical history, performing a physical examination and engaging in medical decision making, as part of the service. In fact, the text following CPT 97802-4 states: "For medical nutrition therapy assessment and/or intervention performed by a physician, see Evaluation and Management or Preventive Medicine service codes." (As noted above, since the Section 105(b), 42 U.S.C. 1395x(vv)(1), requires Medicare-covered visits to be for patients with established illness, only the office visit/consultation codes, not the preventive medicine codes, could be used for a Medicare-covered visit.)

36. To qualify for CPT 99241 or CPT 99213 these 3 components do not need to be at high levels. CPT 99241 is a level one E/M code that has the following, a problem focused history, a problem focused examination, and straightforward medical decision making; CPT 99213 is a level three E/M code that has the following, an expanded problem focused history, an expanded problem focused examination, and medical decision making of low complexity. (71 FR 37211, 37214).

37. Similarly, a registered dietitian who is not a physician will take a problem focused or expanded problem focused medical history, reviewing labs and other reports from the referring physician and interviewing the patient; will perform a limited medical examination, which will include anthropometric measurements, and could also include additional examination such as taking blood pressure or blood glucose, or examining affected body areas such as the skin for diabetic acanthosis nigricans, or for pressure ulcers that may be connected with protein-calorie malnutrition; and engage in straightforward or low complexity medical decision making, which will include prescribing or modifying nutrient and/or micronutrient intake, administration or supplementation, and could include additional medical decision making such as modifying insulin doses to match carbohydrate intake using carbohydrate counting/insulin ratios.

38. Because the levels of the history taking, physical examination and decision making in the visit (whether by a physician who is also a dietitian, or by a dietitian who is not a physician) are often low, the lower levels of medical history, physical examination and decision making contained in the 15-minute consultation code CPT 99241 make the work RVU of that code (current and proposed work RVU of **0.64**) more appropriate than the work RVU of CPT 99213, which has higher levels of history taking, physical examination and decision making (current work RVU of **0.67**, proposed work RVU of **0.92**). Therefore we recommend using the work RVU of CPT 99241.

39. It is also appropriate to use the work RVU of CPT 99241 because time may be the determining factor in assigning the level of the service. When time is the determining factor, the work RVU of CPT 99241 generates the lowest (and therefore most modest) work RVUs for visits lasting 15 minutes, 30 minutes or one hour.

40. The Evaluation and Management Service Guidelines state, under the heading "Levels of E/M Services": "The descriptors for the levels of E/M services recognize seven components, six of which are used in defining the levels of E/M services. These components are: History, Examination, Medical decision making, Counseling, Coordination of care, Nature of presenting problem, Time. The first three of these components (history, examination, and medical decision making) are considered the key components in selecting a level of E/M services."

41. However the Evaluation and Management Service Guidelines state later, under the heading "Select the Appropriate Level of E/M Services Based on the Following", "3. When counseling and/or coordination of care dominates (more than 50%) the physician/patient and/or family encounter (face-to-face time in the office or other outpatient setting or floor/unit time in the hospital or nursing facility), then time may be considered the key or controlling factor to qualify for a particular level of E/M services."

42. Although the definition of medical nutrition therapy services, Section 105(b), 42 U.S.C 1395x(vv)(1), includes three services, "diagnostic, therapy, and counseling services", counseling services will almost always dominate (more than 50%) the encounter. Therefore, time may be considered the key or controlling factor.

43. The following chart compares CPT 99241 to all other office visit/consultation codes that are 15 minutes or divisible by 15 minutes (all other codes are either less than 15 minutes or not divisible by 15 minutes). The chart shows that for both the current and proposed RVUs, the work RVU of CPT 99241 generates the lowest (most modest) work RVUs for visits lasting 15 minutes, 30 minutes or one hour. (70 FR 70458; 71 FR 37218, second-third columns; 71 FR 49232):

CPT Code	15-Minute RVU	30-Minute RVU	One-Hour RVU
99241	**0.64** Current	**1.28** (2 increments)	**2.56** (4 increments)
	0.64 Proposed	**1.28** (2 increments)	**2.56** (4 increments)
99213	**0.67** Current		
	0.92 Proposed		
99242		**1.29** Current	
		1.34 Proposed	
99203		**1.34** Current	
		1.34 Proposed	
99244			**2.58** Current
			3.02 Proposed
99205			**2.67** Current
			3.00 Proposed

The ADA Prefers Using an E/M Code RVU

44. All of the registered dietitians at Midtown are members of our professional society, the American Dietetic Association, and we have observed over the past 6 years that the ADA has consistently communicated its preference for work values based on E/M codes, in particular the level three, 15-minute and 30-minute, office visit codes CPT 99213 and 99203. As CMS observed, "the ADA compared work associated with their services to physician E/M services of CPT 99203 and 99213, which have respective work values of **1.34** and **0.67**." (71 FR 48987, second column).

45. Because CMS stated in the Calendar Year 2006 Final Rule that it was "deferring our decision regarding work RVUs for audiology, speech language pathology and medical nutrition pending further discussion with the specialties", ADA submitted a January 3, 2006 letter (Attachment C). In the letter ADA stated, at page 3, "there is external support for a far more transparent approach to MNT RVUs. AMA indicates in the CPT 2005 publication, 'for medical nutrition therapy assessments and/or intervention performed by a physician, see Evaluation and Management or Preventive Medicine service codes.' If CMS believes the MNT statute for payment must be followed, then the agency should base the RD payment rate on 85% of the total physician RVUs for these codes (eg. E&M code 99203)." Nowhere in that letter are the HCPAC interim recommendations even mentioned.

46. In its March 24, 2006 follow-up letter to CMS (Attachment D), ADA again states its preference for E/M work values (bottom of page 1-top of page 2): "The most straightforward way to correct this anomaly is to establish work values for codes 97802, 97803 and 97804. CMS could crosswalk the work RVU from either the Evaluation and Management codes, or Preventive Medicine codes; the codes physicians are directed to use when they provide MNT services.... Alternatively, CMS could use the HCPAC interim work RVUs for the MNT codes. These values could be used but only with caution since they were not valued as physician services and therefore reflect a discounted service [emphasis supplied]."

47. CMS stated in the Calendar Year 2007 Proposed Rule: "More recently, the ADA requested us to reconsider our decision not to accept the HCPAC recommended work RVUs [emphasis supplied]." (71 FR 48987, second column). A more accurate statement would be: "More recently, the ADA requested us to reconsider our decision not to accept work RVUs."

48. When ADA wrote its March 24, 2006 letter it was not clear whether CMS would establish work values, so in an effort to make CMS comfortable with the concept ADA demonstrated to CMS that there were several sources upon which to base work values. ADA listed four such sources in the following order, first ADA's preference, an E/M code, then a preventive medicine code, then the 2000 RUC survey data, then the HCPAC interim recommended RVUs, if CMS "would adjust the HCPAC work professional services upward to recapture the value of the remaining 15%".

49. The HCPAC recommended work RVUs not increased by 15% were not even one of the alternatives! And the difference in compensation by not increasing by 15% (i.e. dividing by 0.85) is significant because the HCPAC recommended base RVU of **0.45** ÷ 0.85 = **0.53**, or **0.08** RVUs higher.

50. But even if increased by 15%, we submit that physical therapy code-based RVUs are not statutorily appropriate because the statute says that payment to dietitians should be 85% of the amount determined for the same services if provided by a physician.

CMS Not HCPAC Should Determine the Value of the Work RVUs

51. ADA has clearly expressed its preference for a comparison to E/M codes. However, even if ADA had no preference, we submit that CMS has the duty to make a reasoned analysis of whether E/M codes rather than physical therapy codes best describe what a physician who is also a dietitian would report for the service: "we retain the responsibility for analyzing any comments and recommendations received, developing the proposed rule, evaluating the comments on the proposed rule, and deciding whether and how to revise the work RVUs for any given service." (71 FR 37172, first–second columns).

52. If after a reasoned analysis CMS determines that medical nutrition therapy services are closer to physical therapy services than to office visit/consultation services, then so be it. But Midtown respectfully submits that CMS owes the public, the beneficiaries entitled to medical nutrition therapy services, and the registered dietitians and nutrition professionals who may provide such services, a thorough, reasoned analysis of the issue.

53. If CMS allows the HCPAC physical therapy code-based work RVU recommendations to become part of the Final Rule, the ADA will be forced to take the issue back to HCPAC. However, we strongly urge CMS to avoid this situation.

54. First, this will delay by at least one year the establishment of adequate work RVUs. And there is no guarantee that HCPAC will act in time for the 2008 Physician Fee Schedule. HCPAC may take 2 or even 3 years to act, prolonging the lack of access to care for 8,000,000 beneficiaries with diabetes or renal disease.

55. Second, now that these services are recognized as physician services there may be a jurisdictional question as to whether the regular RUC or RUC/HCPAC should decide the issue.

56. Third, CMS is fully competent to make its own determination.

57. Congressman Jose Serrano, the original sponsor of the medical nutrition therapy benefit bills, has reviewed this Comment and joins with our request that "you [CMS] perform a prompt, thorough, reasoned analysis of the appropriateness of the work value to be assigned, so that better access to care may be made available as soon as possible." (Attachment A).

Conclusion

58. The current and proposed malpractice RVU for all 5 Medical Nutrition Therapy codes is **0.01**. When added to the current practice expense RVUs, this makes the total current RVUs **0.48** and **0.19** for the individual codes and groups codes, respectively. (70 FR 70458, 70462; 71 FR 49231, 49235).

59. Midtown submits that the assignment of appropriate work RVUs to these codes should be based on the 15-minute consultation code CPT 99241, using its current and proposed RVU of **0.64** for the individual codes and 40% of that amount (multiply by 2 then divide by 5), or **0.25**, for the group codes. (66 FR 55281, first column).

60. If the proposed practice expenses of **0.12**, **0.10**, and **0.04**, for the individual initial visit, the individual follow-up visits, and the group visits (71 FR 49231, 49235), are added to work RVUs based on CPT 99241 (**0.64** and **0.25**), this would create (including the malpractice RVUs), total RVUs of **0.77**, **0.75** and **0.30**.

61. This would increase provider reimbursement rates for medical nutrition therapy services by about 50%, or perhaps a little less due to adjustments to preserve budget neutrality. (71 FR 37241, first-second columns).

62. With a 50% increase Medicare reimbursement would still be about 25% less than existing market rates but should be sufficient to allow us, and, we believe, the majority of other registered dietitians, to afford to become Medicare providers, and this should provide access to care for the Medicare beneficiaries entitled to these services.

Sincerely yours,

Robert Howard, RD, JD
Managing Partner

BAYLOR
Regional Transplant Institute
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September 22, 2006

Donald H. Romano, Director
Director of Technical Payment Policy
Centers for Medicare and Medicaid Services
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RE: Application for Liver Transplantation Program
by University of Arkansas for Medical Sciences.

Dear Director Romano:

I have reviewed the application submitted by UAMS for approval as a liver transplant center by Medicare and Medicaid services. The application addresses the requirements for Medicare and Medicaid approval according to the Federal Registry of April 12, 1991, Volume 56; Number 71.

The application addresses the nine sections mentioned in the Federal Registry: Patient selection, patient management, commitment, facility plans, experience, and survival rates, maintenance of data, organ procurement, laboratory services and billing.

In general, the UAMS successfully addresses all of these issues. The description for patient selection is satisfactory and patient selection and implementation plan is adequately written. They in particular address abstinence criteria for alcohol and substance abuse that is so prevalent in the patient population today. For management, they discuss clinical transplant coordinator position. The only question I would raise is that they have not addressed how many coordinators they plan to have in order to provide 24/7 coverage for the patients. The patient referral process is well thought out, and so is the patient education plan. They also addressed the history of medication for patients who are financially unable to obtain medication in a successful fashion.

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The process of adding patients to the waiting list is important and is well described and delineated. However, it says under procedure #7 change the chart to orange folder - what does an orange folder mean? As far as infection control, the policy calls for HEPA and closed door for the postoperative patients. It also prevents fresh flowers in the patients' rooms and the plan to do a routine monitoring for nosocomial infections. This seems quite excessive. I am not aware of any established transplant centers, especially not well-known ones, who use such criteria. To the best of my knowledge, no liver transplant center today employs HEPA filters, or such rigorous isolation principles.

The evaluation process is well described. They seem to have almost every specialty involved in the patient selection committee, which is somewhat surprising at this day and age; however, certainly it would provide a comprehensive discussion and evaluation. The whole evaluation process is exhausting and may be overly involved and expensive.

The consent form for liver donor resection is of particular interest. The form lacks several things that ought to be noted. I believe a consent form for living donor donation needs to include nationally and internationally published statistics for mortality. In addition, there is no mention of the risk for major morbidity, including liver transplantation for technical injuries and bile duct injury that may require advanced surgery or even transplantation in the future. This needs to be added.

The transplant manual is comprehensive and addresses most of the issues. It also has complete nursing protocol for the ICU, as well as related post-transplant floor. The treatment protocol includes pathology protocol that is adequate including standards for the performance and review of post-transplant liver biopsies. The infectious disease protocol is comprehensive and well thought out. The infectious disease protocol includes, of course, hepatitis B and hepatitis C protocols.

In the section that relates to patient education, which is quite complete; it describes transplant medications, but they restrain themselves to mention only tacrolimus, mycophenolic acid and prednisone and no alternative agents, which would be prudent. Under mycophenolic acid, they do not mention leucopenia and thrombocytopenia, which are common side effects from mycophenolic acid and mycophenolate mofetil treatment. This needs to be added.

Under the subsection commitment, they have sufficient personnel to embark on this project; signed letters of commitment and intent from the designated liver transplant surgeon, Dr. Wu. They also have the commitment from the liver transplant hepatologist, Dr. Refai, who both meet the criteria for training and experience in liver transplantation. They have provided a table with the transplant team members, which includes administrators, the transplant surgeon, the transplant hepatologist, the transplant coordinators, transplantation administrators, the assistant surgeon, as well as anesthesiologists, the OPO director, psychologist, blood bank, cardiologist, immunologist, infectious disease, internists, radiologists, medicine, nephrologists, oncologists, operating team, pathology, pharmacy and nursing, pulmonary medicine, SICU, social work and vascular surgeon. However, there is no letter of commitment from any one of these individuals. I assume they are all employed by the university and I am sure that they have made a commitment, although; this is not absolutely clear by the application itself.

Facility plans: Apparently, UAMS has initiated new construction, which will not be finished until 2008. Clearly, this should provide sufficient space for the program. It would also put the program under increased risk for Aspergillus infections.

Experience and survival rate: At the time of this submission, they did not have full one-year experience with the first 12 transplants as required by the statute. From May 14, 2005, when the first liver transplant was performed, until June 27, 2006, they have performed a total of 28 liver transplants. The only death was apparently from a motorcycle accident. In addition to the death of the patient, an additional graft has been lost. It is unclear what the cause was for that graft loss and that ought to be reported. The results are truly extraordinary. In fact, the results are better than you could expect by the very most experienced and best liver transplant programs in the United States of America and in the world. Indeed, it raises the question if they are even too good. Did the patients truly need transplants at the time? Arkansas has only one liver transplant center and as such they could allocate the organs to whomever they would like. Hence, they avoided all the complicated cases, which is a practice often done by startup programs.

Maintenance of data: The institution has made a commitment to provide all the data as required by CMS and by UNOS/SRTR.

Organ procurement: They have an existing agreement with the Arkansas Region Organ Recovery Agency for the retrieval, preservation and transportation of the donated organs. The signed contract is included as required by statute.

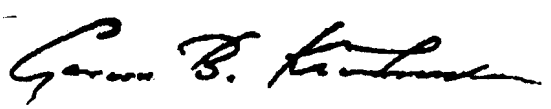
Laboratory services: All the required letters of support and agreement necessary by the program are included in the agreement. However, there is an attachment regarding histocompatibility testing. The turn around for a crossmatch to receive verbal result is 8 hours. This seems to me very long. With cytotoxic crossmatches, we expect to have all our CDC crossmatches back within 4 hours and even when we use flow crossmatches we expect to have them back in 6 hours.

Billing: A statement was made to be sure that Medicare is billed only for approved services.

In summary, the University of Arkansas of Medical Science has submitted an application for Medicare and Medicaid approval of their liver transplant program. The application is complete with a few minor deviations and questions as outlined above. I made the assumption that the involved physicians in the program, as well as the supporting faculty, are covered by the list of submitted names in the application. If, there needs to be a signed commitment from the various chief of services, it can be added. My only question is the outcome data, which are so remarkably excellent. Which raise questions for the reasons I outlined above.

If you have any questions regarding my review, please contact me at (214) 820-1757, or gorank@BaylorHealth.edu.

Yours sincerely,



Goran B. Klintmalm, MD, PhD, FACS

GBK: td

September 29, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
P.O. Box 8010
Baltimore, MD 21244-8010

RE: CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee schedule for Calendar Year 2007 and Other Changes to Payment Under Part B – **"DRA Proposals."**

Dear Dr. McClellan:

As a vascular surgeon who practices in Exeter, New Hampshire and as a member of the Society for Vascular Surgery (SVS), I am writing in response to the publication of CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee schedule for Calendar Year 2007 and Other Changes to Payment Under Part B, specifically the section regarding implementation of Section 5102 (b) (1) of the Deficit Reduction Act (DRA) and the list of imaging services that the Centers for Medicare and Medicaid Services (CMS) has included within the scope of "imaging services" defined by the DRA provision.

I am concerned that CMS has proposed to include non-invasive vascular diagnostic studies, CPT codes 93875 – 93990 and G-code 0365, in the list of imaging codes that are defined by Section 5102(b) of the DRA when in fact these studies contain no imaging or are predominately non-imaging in nature. Given the inclusion criteria that CMS has proposed, there are numerous reasons that these studies should not be listed in Addendum F.

The CPT manual is very clear that non-invasive physiologic studies are performed using equipment that is separate and distinct from the duplex scanner. In a vascular surgeon's practice, we perform physiologic studies on Medicare patients where there are signs and symptoms of peripheral arterial disease and we use physiologic vascular studies, CPT codes 93922, 93923 and 93924 to confirm presence of disease, assess the severity, allow accurate delineation of prognosis and provide a measure of effectiveness of treatments including exercise programs, percutaneous intervention and bypass surgery. Because these codes **do not contain imaging**, CMS should remove them from the list of services included under the imaging provisions of the DRA in the Final Rule, just as it has done in the proposed rule for nuclear medicine services that are "non-imaging diagnostic services" and radiation oncology services that are "not imaging services".

CMS should also exclude duplex scans of arteries (CPT codes 93880, 93883, 93925, 93926, 93930, 93931 and 93990) from DRA because the most important component of these procedures is collection of Doppler velocity data, **a non-imaging ultrasound modality**. For example, CPT 93880 is a non-invasive duplex scan of extracranial arteries; a complete bilateral study. B-mode imaging ultrasound is used to find the arteries in the neck, but non-imaging Doppler-based blood flow velocities are the most important data collected during the exam. Non-imaging Doppler-based blood flow velocities are the most important elements on which arterial stenosis measurements are based, and the stenosis determination is the criterion on which clinical treatment decisions are made. In summary, the single main reason for "imaging" in the carotid duplex scan is to find the correct location to obtain Doppler velocity measurements.

In addition, I believe there is confusion regarding the term "Doppler" and the information that this modality provides to a vascular surgeon for use in diagnosing vascular disease. There are several forms of Doppler ultrasound used in non-invasive vascular diagnosis (continuous-wave Doppler, pulsed-wave Doppler, color-flow Doppler velocity mapping), but all Doppler modalities have one thing in common – they measure blood flow. In the absence of blood flow, the Doppler measures nothing: there is no audible sound, velocity determination or flow mapping. The Doppler does not provide images of body parts. Thus, **Doppler techniques do not meet CMS's definition for inclusion, as these services do not provide "visual" information.** Duplex scans should be excluded from the DRA provisions in the Final Rule because the most important information provided by these tests is based on Doppler.

I recently participated in a survey conducted by the SVS of its members with office-based vascular labs regarding the impact of cuts on non-invasive vascular diagnostic studies, if they are erroneously included under DRA. The dramatic results demonstrate that Medicare beneficiaries' access to these services would be severely affected: 54 percent of vascular surgeons with office-based vascular labs would no longer provide or would reduce vascular laboratory services to Medicare beneficiaries and 24 percent would close the lab entirely or reduce services; 35 percent estimate that Medicare beneficiaries would wait three to four weeks to receive services if they had to go elsewhere and 22 percent estimate that patients would have to travel more than 20 miles to receive suitably high-quality vascular lab studies.

Given this level of impact and the fact that non-invasive vascular diagnostic studies do not meet CMS's proposed criteria for inclusion under DRA and instead meet the criteria CMS is proposing to exclude certain diagnostic services, I respectfully request that CMS remove these codes from Addendum F – Proposed CPT/HCPCS Imaging Codes Defined by Section 5102(b) of the DRA.

I greatly appreciate this opportunity to provide CMS with information and I would be happy to answer any questions. Please do not hesitate to contact me at 603-418-0700.

Sincerely,

Nicholas D. Garcia, MD

Submitter:	**Physician**
Organization:	**Private Practice**
Category:	**Physician**
Issue Areas/Comments:	**Proposed Changes to Reassignment and Physician Self Referral Rules Relating to Diagnostic Tests CMS-1321-P**

Reassignment and Physician Self-Referral

I am commenting on **Proposed Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests** published in the **Federal Register**/ Vol. 71, No. 162/ Tuesday, August 22, 2006/ Proposed rules (pages 49054-49078).

Overview of Current Imaging Abuses
The current Medicare rules, combined with the "perfect storm" of diminishing reimbursement for primary care physicians (PCPs) rapid improvements in digital imaging technologies, and aggressive marketing by imaging companies are currently causing over-utilization of diagnostic tests. The cost of imaging studies is one of the fastest growing health care services and accounts for 10-15% of health care payments. Imaging costs are growing at an annual average exceeding 20%.

In the face of rising practice expenses and diminishing practice reimbursement by Medicaid and third party payers, family physicians, internists, and others have sought additional revenue sources to maintain their incomes. Creating another "service line" by imaging patients seen in their offices is a lucrative, no-risk way to augment incomes. For years these PCPs have referred patients for diagnostic testing (ultrasonography, echocardiography, and nuclear cardiac testing) to hospitals or specialists' offices. PCP's billing and collecting the technical component (TC) and sometimes the professional component (PC) of diagnostic tests substantially increases their revenues. It is easy to do and legal. For example, one recently hired internist's billings were lower than what his group expected and to remedy the situation, he began ordering more diagnostic tests to be performed by his practice. Current practices, if left unchecked, will cost Medicare hundreds of millions or even billions of dollars annually. Follow-up care of these suboptimal tests also exposes elderly patients to suboptimal studies and additional non-invasive testing or invasive procedures. The abusive testing occurs by one of two basic methods.

In a less common and more extreme scenario, a PCP will purchase used, old ultrasound or echocardiography equipment and then attend a two day CME course (see attachment 1) to learn how to interpret studies. It is noteworthy the courses target "Those looking to

significantly increase their in-office earning potential". These courses are not a substitute for the years of training that a radiologist or cardiologist spends to learn to interpret studies. Medicare does not have written requirements demanding that a doctor be board certified in the field that he/she are interpreting, nor does Medicare demand that the equipment be modern. Novice physicians using outdated equipment will be paid for performing the study at the same rate as an expert who performs the study at a first-rate, certified imaging center. In the most egregious examples that I have seen, the physician's interpretation is merely signing the technologist's report! This allows any physician to bill and collect the TC and PC for any Medicare patient. I have been asked within this month where is the cheapest place to purchase imaging equipment by a primary care physician who is interested in entering this lucrative business.

In a very common scenario, an imaging company markets and recruits PCPs to provide them a "turn-key" imaging solution. The imaging company contracts with specialists to provide interpretation of imaging studies at a pre-set, heavily discounted reimbursement rate that the PCP pays the specialist. The imaging company hires technologists. They rent imaging equipment and motor vans to move the technologists and equipment to widely dispersed PCP offices throughout the state or region. Their contracts with PCPs to rent professional services are legal due to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173 Section 952. The Revisions to Reassignment Provisions "allows physicians to reassign payment for Medicare covered services to entities with which they have an independent contractor arrangement, such as a medical group, a physician management organization or staffing company." This rule has spawned a rapidly growing imaging industry (see attachment 2).

In one variation of this insidious arrangement between the medical group and the imaging company, the medical group signs an annual leasing agreement with the imaging company to rent a $1/10^{th}$ or $1/5^{th}$ interest in imaging equipment and a technologist who becomes an independent contractor of the medical group. The group pays the imaging company about $500 for one-half day of service each week or about $1000 for a full day of service each week. The technologist will perform as many echocardiography and ultrasonography studies as possible in that allotted time. As part of the "turn key" approach, the group receives a printed interpretation of the study with the group's name on it interpreted by a specialist. Medicare patients are billed for the TC by the medical group and the PC is billed by the interpreting physician who will occasionally suggest that patients with abnormal studies be seen by them in consultation. Privately insured patients are billed the TC and PC by the medical group with the interpreting doctor compensated by the imaging company at a very low rate. The cunning imaging company, which recruited the PCPs and the interpreting specialists (who are "independently" hired by the primary care physician) and created the "turn-key" operation is not violating Medicare law as it never bills Medicare patients. Its revenues are from the PCP customers. Without such companies the over utilization would be much less. These companies are providing a valued service to the PCPs; however, Medicare is paying for a large portion of the tab.

For an annual payment of $25,000 or $50,000 to the imaging company, the medical group receives four or eight hours of imaging time with the reports included in the price. The PCP must order 2 or 4 studies to pay for the contract and any additional studies represent profit. In this perverse but widespread practice, physicians are better paid to order studies than to treat patients. Incredibly these PCPs would be financially penalized if they do not order enough studies to cover the extra expense of money owed to the imaging company! Ordering additional studies means more revenue and under current Medicare rules, the ordering doctor does not need to know how to interpret the study, how to judge if the equipment or study is technically adequate, or how to treat patients with abnormal studies. Faced with declining payments for the evaluation and management services that the PCP spent years acquiring, this deal is too good—and too legal—to pass up.

These arrangements are facilitated because of technological advancements with the digitalization of imaging equipment. Five to ten years ago, sonograms and echocardiograms were recorded onto video tape. The difficulty of transporting video tapes slowed the growth of the industry. Current machines allow for digital capturing of imaging and transmission to a server. The readers of the studies interpret the images and generate the reports by logging on the server, and thus the readers can be based in distant locations. Readers do not have the benefit of seeing the patients, obtaining medical histories, or reviewing prior studies before rendering their interpretations.

Nuclear cardiology is undergoing a similar rapid evolution into a "service line" for PCPs due to technological advances and outdated reimbursement rules. Until recently, nuclear cardiology testing required the purchase of an expensive gamma camera which weighed thousands of pounds and needed to be kept at a constant temperature. Therefore, leased arrangements for nuclear cardiology testing (exercise or pharmacological nuclear testing) were virtually non-existent. Technological advances have created mobile nuclear cameras that are easily transported from van to office thus qualifying for the "in-office ancillary service" exemption. Digitalized nuclear cardiac images can be read remotely by independent contractors utilizing the reassignment provision allowed by the Medicare Modernization Act of 2003. Aggressive marketing by "turn key" imaging companies showing small practices how to generate "greater revenues" at "no cost to your practice" is contributing to the rapid growth of outpatient nuclear cardiology services. Mobile nuclear testing is now being done in primary care physicians' offices, and expectedly there will be a great increase in the utilization of these studies. A company manufacturing mobile nuclear imaging equipment discussed their reliance of marketing studies to PCPs by imaging companies as being vital in their annual report (see attachment 3).

Patients with an abnormal sonogram or echocardiogram performed by the PCP are referred to a specialist who must often repeat the study as the images that the written report is made from are not available. The study is repeated with additional cost but without risk to the patient. Unfortunately, when a patient with an abnormal nuclear cardiology study is referred for evaluation, the very expensive test cannot be repeated and so the patient frequently undergoes invasive cardiac catheterization. Other problems with the treating specialist reviewing a test such as an echocardiogram or nuclear cardiology

study done elsewhere and the test being unavailable include: not knowing the qualification of the readers, liability of not pursuing abnormal studies, not having access to accompanying diagnostic data, and the disconnection of the patient being told that a study is abnormal by one interpreting physician that he/she never meets and subsequently being told that a follow-up study is normal.

The problem has become so widespread that several private payers have begun addressing the problem. Highmark Blue Cross of Pennsylvania is not allowing some diagnostic testing to be performed in non-specialist offices. Highmark Blue Cross, Aetna, and other Blue Cross subsidiaries also reacted in 2005 by contracting with National Imaging Associates (NIA) to manage imaging services. Some insurance companies adopted a new credentialing criterion for participation in their managed care network. Highmark Blue Cross expects a 25% decrease in utilization of imaging services as a result of eliminating duplication of services or elimination of unnecessary services. TUFTS HealthPlan in Massachusetts similarly uses NIA, as well as a strict service specific credentialing process for outpatient facilities, to promote reasonable and consistent quality of imaging services (see attachments 4 and 5).

I have several comments on different points in the Reassignment and Self Referral document. The portion of the document is cited in bold type with my suggestions for diminishing over utilization following.

#1 "We are concerned that allowing physician group practices or other suppliers to purchase or otherwise contract for the provisions of diagnostic tests and then to realize a profit when billing Medicare may lead to patient and program abuse in the form of over utilization of services and result in higher costs to the Medicare program." (Page 49054 REASSIGMENT AND PHYSICIAN SELF-REFERRAL)

Per **section 1877(b) (2) (A) (ii) (I) of the Act,** the "in-office ancillary services exemption" for self-referral was intended to allow physicians to bill and collect for **"DHS that are ancillary to the physician's core medical practice in the locations where the core medical services are routinely delivered."** As intended, cardiologists are allowed to perform and interpret echocardiography and nuclear cardiology testing in their offices. Vascular surgeons are allowed to perform and interpret carotid sonograms in their offices. PCPs are allowed to perform and interpret chest x-rays in their offices.

PCPs, who do not have cardiologists or radiologists as "members" of their groups, are hiring interpreting specialists as independent contractors to skirt this rule. These interpreting physicians as independent contractors are "physicians in the group" but not "members of the group". As such, their services do not qualify for "the full range of services test".

Nonetheless, as the rule is presently being interpreted throughout the United States, PCPs are performing a large number of ultrasounds, echocardiograms, and nuclear cardiac tests in their offices that they are not qualified to interpret. They are billing and collecting for these studies. A referring physician should not be able to self-refer a study which no "member" of their group is able to interpret, since the inability to interpret a study clearly identifies a study which is not core to that physician's or that physician group's medical practice. Explicit clarification of this rule may attenuate the high risk of inappropriate referrals for DHS.

A better step would be for Medicare to immediately require minimal standards such as board certification in cardiology, radiology, or nuclear medicine (or completion of training in a cardiology, radiology, or nuclear medicine accredited program) for billing the TC or PC of diagnostic tests such as nuclear stress testing. Board certification in cardiology would be required to interpret echocardiograms. Board certification in radiology would be required to interpret ultrasound with the allowance that vascular surgeons and cardiologists trained in vascular medicine be allowed to interpret vascular ultrasound.

Board certification in radiology, nuclear medicine, or cardiology with a nuclear license would be required to interpret nuclear cardiac testing. The residency training of an internist or family practitioner does not allow one to become competent in these imaging modalities and their board certification evaluation does not test for proficiency in interpreting these tests. This rule would virtually eliminate PCPs lacking adequate training in specific forms of medical imaging from performing studies on unsuspecting Medicare patients. Rules regarding who is qualified to interpret studies will ultimately be needed to reduce this type of patient abuse.

In the future, to better ensure high quality of imaging studies, Medicare could also require that the TC would only be paid to laboratories that were accredited by the appropriate certifying board and had at least one group member certified in that subspecialty of imaging (echocardiography, nuclear cardiology, or vascular medicine) by a nationally recognized medical board. As previously noted some insurance companies are moving in this direction.

The PC would only be paid to physicians that were certified in the imaging subspecialty and had the same billing number as the group that produced the TC. Additional certification of expertise exists for vascular labs, echocardiography labs, and nuclear cardiology labs. Linking demonstrable quality to payment could be considered as part of the Pay for Performance initiative. Unlike my other suggestions, these requirements should be discussed with representatives of the appropriate professional societies, and implementation not begun until 2008 or 2009 to allow physicians time to make arrangements to obtain certification.

#2 "Second, we would also require that, in order to bill for the TC, the billing entity be required to perform the interpretation. Third, we considering further amendments to 424.80(d) that would impose certain conditions on when a physician or medical group can bill for a reassigned PC of a diagnostic test."(Page 49056 REASSIGMENT AND PHYSICIAN SELF-REFERRAL)

I strongly support these additional recommendations. However, I again point out that by not requiring that only a qualified physician may interpret the test, Medicare would allow payment of both TC and PC to non-qualified physicians whose interpretation may fundamentally consists of signing the report prepared by a technologist or another physician hired by an imaging company. Not limiting who is paid for interpreting studies allows for legal payment to an urologist for interpreting a carotid ultrasound or an orthopedist for interpreting a cardiac imaging study!

#3 "In particular, we are soliciting comments as to whether diagnostic tests in the DHS category of radiology and certain other imaging services should be excepted from any those provisions; whether the proposal in whole or in part should apply only to pathology services; whether any of these provisions should apply to services performed on the premises of the billing entity and if so, how to define the premises appropriately."(Page 49056 REASSIGMENT AND PHYSICIAN SELF-REFERRAL)

With the advent of highly mobile imaging equipment that produces digital images that can be loaded onto a server and then literally interpreted anywhere in the world via the internet, it is crucial to define premises precisely. My suggested definition of premises is "the place where the diagnostic testing is both performed and interpreted". I recommend that for a physician or medical group to bill the TC or PC of a diagnostic test, the physician or medical group must interpret the study within the same building that the test was performed and use the same group billing number for the TC and PC. This would

more strictly define premises and make it much more likely that the interpreting physician has a relationship with and direct access to the Medicare patient receiving outpatient diagnostic testing.

Medicare should make a national coverage decision to deny payment of any DHS study which has the PC and TC billed by separate entities. This will swiftly bring the ruling changes enacted to the attention of the PCPs, imaging companies, and interpreting specialists in a way that no other action will. This ruling will also likely have the same effect for "pods". Withdrawing reimbursement for these activities remove the primary motivating reason for their existence.

#4 "We are soliciting suggested regulatory text for the proposal under consideration involving purchased test interpretations, as well as any other comments regarding the appropriate scope of the provisions under consideration."(Page 49056 REASSIGMENT AND PHYSICIAN SELF-REFERRAL)

The ability of PCPs to lawfully purchase test interpretations unintentionally led to the rapid growth and over utilization fueled by imaging companies which now are able to provide "turn-key" diagnostic testing services. Making it unlawful for physicians to bill for interpretation of tests that they do not perform themselves independently would lead to correcting this rapid growth of diagnostic testing. As stated previously, to better prevent patient abuse, Medicare should set guidelines as to who is qualified to interpret DHS studies.

#5 "Similarly, section 1877(b)(2) of the Act authorizes the Secretary to determine additional terms and conditions relating to the supervision and location requirements of the in-office ancillary services exemption as may be necessary to prevent a risk of program or patient abuse."(Page 49056 REASSIGMENT AND PHYSICIAN SELF-REFERRAL)

I would like to propose two comments. First, Medicare can also reduce the risk of patient abuse by requiring that the interpreting physician have direct supervision of the study. Currently Medicare requires general supervision of ultrasound and echocardiography so that the distant interpreting physician or the PCP can be said to be overseeing the study. Of course, the PCP does not have the knowledge base to immediately answer the technologist's questions or to ask for additional images while the patient is in the office. Since many of these abusive studies are interpreted tens, if not hundreds, of miles away from the site of imaging, requiring that the physician or equally qualified partner interpreting the test and billing the PC be directly available helps to solve this problem. Since hospitals are covered by different rules than doctor's offices, there would be no harm to rural hospitals having difficulty attracting full-time specialists.

As previously stated, with the advent of highly mobile imaging equipment that produces digital images that can be loaded onto a server and then literally interpreted anywhere in the world via the internet, it is crucial to define premises precisely. My suggested definition of premises is "the place where the diagnostic testing is both performed and

interpreted". I recommend that for a physician or medical group to bill the TC or PC of a DHS, the physician or medical group must interpret the study within the same building that the test was performed and at least one member of the group is appropriately board certified. This would more strictly define premises and make it much more likely that the interpreting physician has a relationship with and direct access to the Medicare patient receiving outpatient diagnostic testing, as well as the skills required to interpret the study.

Second with the current practice of patient abuse in mind, Medicare should more explicitly define "supervising physician" and "incident to". Currently, the Medicare Carriers Manual Section 2050 Part 3 Chapter 1-3 defines **Incident to Physician Professional Services**. The last revision was August 28, 2002. It reads: **"Incident to a physician's professional service means that the service or supplies are furnished as an integral, although incidental, part of the physician's personal professional services in the course of diagnosis or treatment of an injury of illness."**

If general supervision is maintained as the standard for non-stress diagnostic testing services, and if the "incident to" physician lacks the expertise to interpret the test, and if the interpreting physician is not on site and has never met the patient to establish an "incident to" diagnostic procedure, then who is supervising the technician or Midlevel Provider (MLP)? If the interpreting physician is the "incident to" physician, are Stark laws violated because the interpreting physician has never met the patient to establish the required relationship needed to order the diagnostic study? If the technician is operating under the "supervision" of the ordering physician, who does not have the knowledge and qualifications to "supervise" the technician or MLP, how disingenuous is this?

A "supervising physician" should be a physician with the expertise in an imaging modality to indeed supervise the MLP, that is to, improve the quality of the studies of the MLP by providing feedback and critiquing his/her work. This would therefore require the "supervisor" to indeed be an expert in the field, someone who is able to interpret the study independently. He/she would have credentials from a nationally recognized board which would have tested and acknowledged his/her expertise.

The loose interpretation of "general supervision" today allows any physician to "supervise" any procedure. A dermatologist could "supervise" a cardiac ultrasound, a procedure he/she may never have seen. In this case the dermatologist would then be able to bill Medicare for the cardiac ultrasound using the "in-office ancillary services" exemption. In this scenario, the interpreting physician would be miles away, and probably would have never met the patient.

Medicare needs to explicitly define who may qualify as a "supervising physician" and which DHS services may be "ancillary" to a physician's core medical practice. Private insurance companies have produced professional provider privileging guidelines (see Attachments 4 & 5), and Medicare should do the same.

#6 "The number of IDTF's billing Medicare in California alone increased more than 400 percent from 2000 to 2005. The increased number use of IDTF services has not

lowered the use of diagnostic testing within other settings."(Page 49060 REASSIGMENT AND PHYSICIAN SELF-REFERRAL)

Analogous to the rise noted with IDTF's billing, I expect that analysis of the tests ordered by zip code would see a significant increase once the PCPs practicing in that zip code began providing the diagnostic tests in their offices independently. The growth in these zip codes would far exceed the expected growth in imaging services from population growth or medical necessity from aging. Moreover, there is a financial incentive to cut costs by leasing or buying older, cheaper equipment that is used on a part-time basis.

In summary, Medicare should adopt these following policies to reduce abuse of testing as well as to improve the quality of diagnostic imaging that Medicare recipients receive.

1) Most importantly, Medicare should make a national coverage decision to deny payment of any DHS study which has the PC and TC billed by separate entities. This will swiftly bring the ruling changes enacted to the attention of the PCPs, imaging companies, and interpreting specialists in a way that no other action will. This ruling will also likely have the same effect for "pods". Withdrawing reimbursement for these activities remove the primary motivating reason for their existence.

2) Medicare should mandate that only doctors who have completed qualified training at accredited programs and who are board-certified or board-eligible in the designated specialties could bill the TC or PC for DHS. Medicare should develop professional provider privileging guidelines similar to those developed by private insurers. These guidelines will establish the "ancillary" services that are "core" to "member" physicians' medical practice.

3) Medicare should explicitly define "incident to" and "supervising physician" as noted in Comment #5.

4) Although not mentioned in the comments, Medicare should reverse its 2002 Fee Schedule which liberalized the "incident to" rules so that ancillary personnel (the technologists, or MLP performing the diagnostic tests) no longer had to be a W-2 employee of the group billing for TC. Requiring the technologist or MLP performing the test to be a W-2 employee of the medical group billing the TC and/or PC will curb the proliferation of the for-profit imaging companies.

Attachment 1

Attachment 2

Attachment 3

Attachment 4

Attachment 5

Attachment 1

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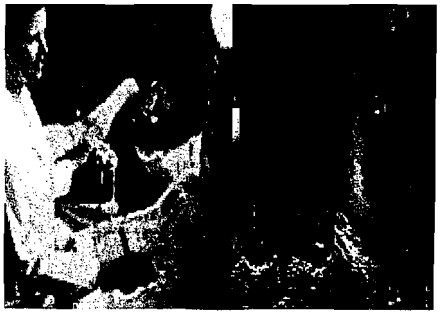

This 2-day hands-on exposure to adult echocardiography will allow the primary care physician to have the techniques to perform in office, and tools to interpret their own cardiac ultrasound exams. These proficiencies can take advantage of the significant reimbursements for these professional and technical insurance components of this procedure.

With didactic instruction, and hands-on instruction in the essentials of the adult echocardiogram, you should feel confident in using this procedure in the office setting. These essentials include: instrumentation, 2-D gray-scale anatomy, M-mode measurements, and hemodynamics including PW, CW, and Color Doppler. You will also be provided basic principles of LV function, acquired valvular disease, coronary artery disease, and a host of other pathogies.You will receive valuable hands-on intructruction with live patient volunteers, to allow you full understand the subtleties of the cardiac echo. You will be able to provide your patients timely and accurate information concerning their cardiac status, as well as billing the insurance companies for these vital services.

Who should attend?

- Those looking to significantly increase their in-office earning potential.
- Primary care physicians, physician assistants, or any medical professional looking to increase their knowledge of adult echo.
- PCPs looking to provide vital accurate, and timely diagnosis of cardiac symptoms to their patients.
- PCPs who wish to gain technical proficiencies in performing and interpreting echo exams.
- PCPs who are looking for the ability to bill for these in office procedures.

Objectives
Upon completion of this workshop the attendee should be able to:

1. Significantly increase the revenue generated in your office, with your current patient population.
2. Quickly and accurately diagnosis cardiac pathologies with ultrasound.
3. Appreciate the fundamental of the ultrasound machine and their control manipulations.
4. Understand the basics of ultrasound physics, gray-scale anatomy, and normal from abnormal 2-D measurements.
5. Recognize spectral wave forms produced from PW, CW, and color Doppler.
6. Recognize acquired pathologies of the heart valves, and the left ventricle.
7. Use essential information to make an educated decision on leasing purchasing an ultrasound machine, or consulting with an outside service to handle these procedures in your office.

Faculty
Guest speakers and additional faculty members not listed may also participate in the training program.

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Cancellation Policy
Your registration will not be valid and confirmed until your course fees have been received. There are no refunds given for workshops Programs, or other programs as well. Credit will be applied to any future program. Empire Medical Training, Inc. must be notified 24 hou any cancellation in order to be credited for any future programs. There are no credits or refunds for "No Shows" the day of scheduled fees can be transferred to another individual, or to another activity date. Empire Medical Training, Inc. is not responsible for nont refundable airline tickets or hotel accommodations purchased for attendance of this activity. Should it be necessary for Empire Medical

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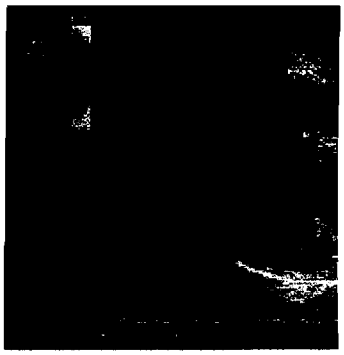
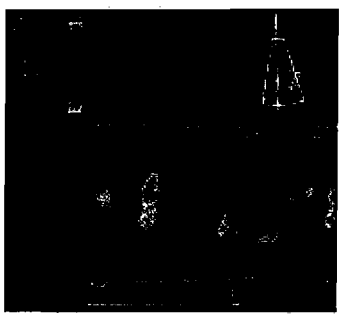
Ultrasound In Your Office

Offering diagnostic medical ultrasound to your patients doesn't mean that you have to make a $100,000 plus investment in buying or leasing equipment and hiring an employee to operate it.



With Professional Ultrasound Imaging's mobile service, you can offer your patients today's most advanced digital ultrasound equipment, and skilled sonographers to operate it, in the convenience of your office.

This can quickly and easily be done at no cost to your practice. And if you or a colleague are qualified to interpret your own ultrasound examinations, even greater revenues can be realized.



PUI offers ultrasound service for the following modalities:

1. **Echocardiography**
2. **Vascular (Carotid and Peripheral)**
3. **Abdominal**
4. **Obstetrical**
5. **Gynecological**
6. **Urological**

- By the day, week, month or bi-monthly in your office.
- A convenience to your patients. No driving to an alternate location.
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- No cost to your practice to begin offering professional ultrasound service.
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Billing and Reimbursement

We offer a variety of billing programs and options, and are always willing to work with you, your staff and patients to customize a program that meets your specific needs.

Here are several examples:

- If we provide our equipment and personnel:
  - We can bill patients and/or their insurance carrier directly
  - We can bill your practice a flat rate per study fee - usually 85% of the Medicare allowable for "locality 28" (Tarrant County). You in tum bill the patient and/or their insurance carrier. Medicare classifies this as a purchased service. Your practice keeps the difference between our fee and what you recover from the patient or their insurance carrier.
  - If you or a colleague are qualified to do your own interpretations, we bill the technical component only, and your practice can bill the professional component.
- If we provide personnel only, full day and half day rates are available, and billed directly to your practice.
- Accreditation or consulting services - rates vary please call or contact us: info@mobilepui.com for a quote.
- Training, lectures and presentations - rates vary, please call or contact us: info@mobilepui.com for a quote.

Terms are net 30 days from date of service unless otherwise arranged. We accept Visa, MasterCard, Discover and American Express cards.

For more on Student Athlete Cardiac Screenings visit www.TheHeartToPlay.com.

changes, our senior management team has not worked together as a group for a significant length of time. If our new management team is unable to work together effectively to implement our strategies, manage our operations and accomplish our objectives, our business, operations and financial results could be severely impaired.

Furthermore, our future growth will depend in part upon our ability to identify, hire and retain nuclear imaging technologists, certified cardiographic technicians, nurses, radiation safety officers, engineers, management, sales personnel and other highly skilled personnel.

Hiring qualified management and technical personnel will be difficult due to the limited number of qualified candidates. Competition for these types of employees, particularly nuclear imaging technologists and engineers, is intense in the medical imaging field. Given the competition for such qualified personnel, we cannot assure you that we will be able to continue to attract, hire and retain the personnel necessary to maintain and develop our business. Failure to attract, hire and retain key personnel could have an adverse effect on our business, financial condition and results of operations. In addition, we have experienced an increasing rate of employee turnover, currently at an annualized rate of above 40 % for the combined service and product segments. If we are unable to reverse this trend, our business and financial condition could be seriously affected.

Our imaging systems and DIS services may become obsolete, and we may not be able to timely develop new products, product enhancements or services that will be accepted by the market.

Our nuclear imaging system and DIS services may become obsolete or unmarketable if other products or services utilizing new technologies or the development of hybrid imaging modalities, such as those combining PET and CT or SPECT and CT, or any other imaging modality, are introduced by our competitors or new industry standards emerge. We have recently observed a moderate decline in the market for single-headed imaging systems, and we cannot assure you that we will be able to compensate for this decline by introducing alternative or more competitive products. Our technical know-how and intellectual property have limited applications. Furthermore, although our nuclear imaging systems and DIS services are principally targeted towards the cardiology market, internal medicine practices have become an increasingly significant portion of the nuclear imaging market. We cannot assure you that we will be able to develop or market successful new products and services or enhancements to our existing products. Nor can we assure you that our future products and enhancements will be accepted by our current or potential customers or by the third-party payors who financially support many of the procedures performed with our products. Any of these circumstances may cause us to lose customers, disrupt our business operations and harm our product sales and services. To be successful, we will need to enhance our products or services and to design, develop and market new products that successfully respond to competitive developments, all of which efforts may be expensive and time consuming.

Highmark
Professional Provider Privileging Guidelines

Purpose

The following guidelines are intended to promote reasonable and consistent quality and safety standards for the provision of imaging services. Highmark will not reimburse providers for imaging services performed if they do not satisfy the following guidelines. These guidelines affect all Highmark members except those covered under traditional indemnity plans.

General Requirements for Imaging Providers

- All imaging providers must provide a written report within 10 business days from date of service to the ordering provider. (Mammography reports must be completed within 30 days, per Mammography Quality Standards Act (MQSA) guidelines.)
- All imaging facilities must have a documented Quality Control Program inclusive of both imaging equipment and film processors.
- All imaging facilities must have a documented Radiation Safety Program and As Low As Reasonably Achievable (ALARA) Program.
- All imaging facilities utilizing equipment producing ionizing radiation must have a current (within 3 years) letter of state inspection, or calibration report, or physicist's report.
- Highmark Medical Policy will apply to the delivery of services detailed in the guidelines.
- All imaging providers must be Highmark credentialed (hereinafter referred to as "credentialed").

Guidelines Specific to Plain Films

- Providers must have a state certified or American Registry of Radiologic Technologists (ARRT) certified technologist on-site taking all films, or must arrange for a credentialed radiologist to over-read all films within 5 business days from date of service.
- At minimum, an automatic processor must be used to develop all analog plain films.

Guidelines Specific to Bone Densitometry

- Bone Densitometry must be performed by hospitals, or by credentialed radiologists, endocrinologists, rheumatologists, obstetricians/gynecologists, orthopedists, internists, and family physicians.
- Must be performed on an axial Dual Energy X-ray Absorption (DEXA) system or a Quantitative CT.
- At least one physician from each practice location must be a credentialed radiologist or achieve certification by the ISCD (International Society for Clinical Densitometry), and one technologist from each practice location must be ARRT certified or achieve certification by the ISCD (International Society for Clinical Densitometry) within one year of Provisional acceptance in the Privileging Program. *[Note: Practice must submit evidence of application for accreditation within 3 months of receipt of letter indicating Provisional acceptance.]*

Guidelines Specific to Nuclear Cardiology

- Nuclear cardiology practices must employ at least one physician who is credentialed in diagnostic radiology, nuclear medicine or has received certification by the Certification Board of Nuclear Cardiology (CBNC).
- Nuclear cardiology practices that do not meet the above criteria will be considered for participation upon submitting evidence that at least one physician has satisfied the Level II training in Nuclear Cardiology as recommended in the American College of Cardiology/American Society of Nuclear Cardiology, Core Cardiology Training Symposium (COCATS) Training Guidelines.
- Nuclear cardiology imaging systems must have the capability of assessing both myocardial perfusion and contractile function (ejection fraction and regional wall motion).
- Cardiac stress tests must be performed under the direct supervision of a credentialed physician who has a current Advanced Cardiac Life Support (ACLS) certification.
- Nuclear cardiology practices must provide a copy of a Radioactive Materials License that indicates the practice address and the name of the nuclear cardiology physician(s) performing and/or

interpreting nuclear cardiology studies. The address and physician name(s) must be the same as those listed on the Privileging Application completed by the practice.

- Nuclear cardiology practices must use a technologist who is certified in Nuclear Medicine through the ARRT, Certified Nuclear Medicine Technologist (CNMT) or Nuclear Medicine Technology Certification Board (NMTCB) or licensed by the state in nuclear medicine technology.
- Nuclear cardiology practices must achieve accreditation by ICANL (Intersocietal Commission for the Accreditation of Nuclear Cardiology Laboratories) or the ACR (American College of Radiology) within two years of Provisional acceptance in the Privileging Program. *[Note: Practice must submit evidence of application for accreditation within 3 months of receipt of letter indicating Provisional acceptance.]*

Guidelines Specific to Echocardiography/Stress Echocardiography

- Echocardiography must be performed by physicians credentialed in diagnostic radiology or cardiology, or under the personal supervision of a physician credentialed in diagnostic radiology or cardiology.
- Echocardiography systems must have Color Flow Doppler capability.
- Stress echocardiography must be performed under the direct supervision of a credentialed physician who has a current Advanced Cardiac Life Support (ACLS) certification.
- Echocardiography practices must achieve accreditation by ICAEL (Intersocietal Commission for the Accreditation of Echocardiography Laboratories) within two years of Provisional acceptance in the Privileging Program. *[Note: Practice must submit evidence of application for accreditation within 3 months of receipt of letter indicating Provisional acceptance.]*

Guidelines Specific to Peripheral Vascular (PV) Ultrasound

- PV Ultrasound must be performed by physicians credentialed in diagnostic radiology, vascular surgery, cardiology or neurology, or under the personal supervision of a physician credentialed in diagnostic radiology, vascular surgery, cardiology or neurology.
- PV Ultrasound providers must employ a sonographer certified by the American Registry of Diagnostic Medical Sonographers (ARDMS) or ARRT.
- PV Ultrasound systems must have Color Flow Doppler capability.
- PV Ultrasound providers must achieve accreditation by ICAVL (Intersocietal Commission for the Accreditation of Vascular Laboratories) or the ACR (American College of Radiology) within two years of Provisional acceptance in the Privileging Program. *[Note: Practice must submit evidence of application for accreditation within 3 months of receipt of letter indicating Provisional acceptance.]*

Guidelines Specific to Obstetrical/Gynecological (OB/GYN) Ultrasound

- OB/GYN Ultrasound must be performed by credentialed radiologists, obstetricians, gynecologists, and family physicians, or under the personal supervision of credentialed radiologists, obstetricians, gynecologists, and family physicians.
- Practices that achieve accreditation in Obstetrical and/or Gynecological Ultrasound by the AIUM (American Institute of Ultrasound in Medicine) or ACR (American College of Radiology) within one year of Provisional acceptance in the Privileging Program, are eligible to be reimbursed for certain imaging procedures as specified in the Obstetrics II Diagnostic Imaging Privileging (DIP) Level. *[Note: Practice must submit evidence of application for accreditation within 3 months of receipt of letter indicating Provisional acceptance.]*
- Practices that do not achieve accreditation are eligible to be reimbursed for limited OB/GYN ultrasound procedures only.

Guidelines Specific to Urological Imaging

- Urological imaging must be performed by credentialed radiologists and urologists or under the personal supervision of credentialed radiologists and urologists.
- Contrast enhanced procedures must be performed under the personal supervision of a credentialed physician who has a current Advanced Cardiac Life Support (ACLS) or Advanced Radiology Life Support (ARLS) certification.

- Practices that employ a technologist or sonographer certified by the ARDMS or ARRT are eligible to be reimbursed for certain imaging procedures of the abdomen, pelvis and genitalia, as specified in the Urology II Diagnostic Imaging Privileging (DIP) Level.
- Practices that do not employ a technologist or sonographer certified by the ARDMS or ARRT are eligible to be reimbursed for prostate ultrasound only.

Guidelines Specific to Mammography

- Mammography facilities must have a current MQSA certificate issued by the FDA.
- Diagnostic mammography may only be performed under the personal supervision of a credentialed radiologist.

Guidelines Specific to Breast Ultrasound

- Breast Ultrasound may only be performed by a credentialed radiologist, or a credentialed surgeon who has breast ultrasound certification from the American Society of Breast Surgeons (ASBS).
- Practices that do not have a credentialed surgeon who has breast ultrasound certification from the ASBS, must achieve accreditation in breast ultrasound by the ACR (American College of Radiology). within one year of Provisional acceptance in the Privileging Program. *[Note: Practice must submit evidence of application for accreditation within 3 months of receipt of letter indicating Provisional acceptance.]*

Guidelines Specific to Positron Emission Tomography (PET)

- PET must be performed by a hospital; or partially owned by a hospital as part of a joint venture or other partnership; or owned and operated by an oncology practice clinically affiliated with hospital or community based cancer treatment programs; or there is an access need.
- PET facilities must employ technologists certified in Nuclear Medicine through the ARRT, CNMT or NMTCB or licensed by the state in nuclear medicine technology.
- Only high performance full ring PET systems will be considered.
- PET scan providers must achieve accreditation by ICANL (Intersocietal Commission for the Accreditation of Nuclear Laboratories) or the ACR (American College of Radiology) within two years of provisional acceptance in the Privileging Program. *[Note: Facility must submit evidence of application for accreditation to NIA within 3 months of receipt of letter indicating Provisional acceptance.]*

Guidelines Specific to Fluoroscopy

- Fluoroscopy must be performed by, or under the personal supervision of, a credentialed radiologist.

Guidelines Specific to CT and MR

- CT, and MR must be performed at a practice site that provides at least five of the following modalities:
  - ✓ Plain Films or DEXA (either or both count as one)
  - ✓ General or OB/GYN Ultrasound (either or both count as one)
  - ✓ Peripheral Vascular (PV) Ultrasound
  - ✓ Echocardiography/Stress Echocardiography (either or both count as one)
  - ✓ Mammography
  - ✓ Computed Tomography (CT)
  - ✓ Magnetic Resonance Imaging/Angiography (MRI/MRA)
  - ✓ Fluoroscopy
  - ✓ Nuclear Medicine/Nuclear Cardiology
- Hours of operation requirement - Must offer diagnostic imaging services for a minimum of 40 hours per week.
- Must employ an appropriately licensed or certified technologist (state certified, ARRT, ARDMS, NMTCB).
- If offering MRI services, must also provide MRA capability.

- If offering MRI services, must achieve accreditation by the ACR (American College of Radiology) for MRI within one year of Provisional acceptance in the Privileging Program. *[Note: Practice must submit evidence of application for accreditation within 3 months of receipt of letter indicating Provisional acceptance.]*
- Must be staffed on-site by a credentialed radiologist who has a current Advanced Cardiac Life Support (ACLS) or Advanced Radiology Life Support (ARLS) certification during the hours outlined in the hours of operation requirement and whenever contrast enhanced procedures or diagnostic mammography are performed (including during non-standard hours).
- The practice location is not required to have an on-site radiologist when the practice location utilizes teleradiology and meets the following requirements:
  - A Highmark credentialed physician:
    - √ is on-site during normal business hours (40 hours per week minimum).
    - √ is a member of the imaging provider group.
    - √ is available for patient, referring physician and teleradiologist consultation.
    - √ has a current ACLS or ARLS certification.
    - √ is on-site when contrast enhanced procedures or diagnostic mammography are performed.
  - The radiologist performing the imaging reading services via teleradiology:
    - √ is credentialed by Highmark and licensed in the state where the imaging site is physically located and where diagnostic services are rendered to the patient.
    - √ is a member of the imaging provider group.
    - √ is dedicated to providing radiology services via teleradiology during the practice location's normal business hours (40 hours per week minimum).
    - √ is available for consultation with the imaging practice, ordering physician and patient at the time of service during the practice location's normal business hours (40 hours per week minimum).
  - Images must be transmitted in a real-time or near real-time mode (< 2 minutes) to ensure that the interpreting radiologist can collaborate with the rendering physician and radiology technicians performing the studies.
  - At a minimum, sites must be connected via broadband or the necessary bandwidth to ensure real-time or near real-time image availability to the radiologist (< 2 minutes).
  - When a teleradiology system is used to render the official interpretation, there is no clinically significant loss of data from image acquisition through transmission for final image display.
    - Sites must have a PACS (picture archiving and communications system)
    - Sites must have minimum monitor resolution (matrix) of 512 x 512 at 8-bit pixel depth for MR, CT, nuclear medicine, fluorography and 2.5 lp/mn at 10-bit pixel depth for plain film.

- The above guidelines do not preclude credentialed cardiologists from performing echocardiography/stress, echocardiography, peripheral vascular ultrasound, arterial angiography, and nuclear medicine/nuclear cardiology diagnostic services at this practice site.

Guidelines Specific to Practices Specializing in Women's Health

- Must provide at least the following three modalities:
  - ✓ Mammography
  - ✓ OB/GYN Ultrasound
  - ✓ DEXA
- Facilities must have a current MQSA (Mammography Quality Standards Act) certificate issued by the FDA.
- Diagnostic mammography may only be performed under the direct supervision of a credentialed radiologist.
- Must employ an appropriately licensed or certified technologist (state licensed, ARRT, ARRT (M), ARDMS).
- Must achieve accreditation in Obstetrical and/or Gynecological Ultrasound by the AIUM (American Institute of Ultrasound in Medicine) or ACR (American College of Radiology) within one year of

Provisional acceptance in the Privileging Program. *[Note: Practice must submit evidence of application for accreditation within 3 months of receipt of letter indicating Provisional acceptance.]*

Providers Utilizing Mobile Services

Providers utilizing mobile services will not be considered for participation except as follows:

- FDA certified mobile mammography

Additional Provisions:

Highmark will only reimburse providers for diagnostic imaging services if the services are provided on imaging equipment (i) owned by the provider or (ii) leased by the provider on a full-time basis. Owned or leased on a full-time basis is defined as (a) the provider has possession of the equipment on the provider's property and the equipment is under the provider's direct control and (b) the provider has exclusive use of the equipment, such that the provider and only the provider uses the equipment.

"Personal supervision" means that the provider must be in the immediate vicinity so that he or she can personally assist in the procedure, or to assume the primary care of the patient, if necessary. (Source: Highmark Medical Policy Z-27)

All imaging providers are subject to unannounced site inspections. Those providers who are found to have misrepresented information on their Privileging Application may be subject to termination of imaging privileges.

The Highmark Professional Provider Privileging Guidelines are not intended to disadvantage any specialist from providing imaging services.

Tufts Health Plan Imaging Privileging Program

Imaging Privileges for Non-radiologists

The Tufts Health Plan Imaging Privileging Program is a utilization management tool that addresses quality and utilization issues related to non-emergency, outpatient diagnostic imaging provided by non-radiologists. The program's goal is to enhance quality and patient safety, assure the appropriateness of tests, and improve cost-effectiveness while minimizing disruption of health care delivery. Privileging is a condition of payment; however, claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral and utilization management guidelines when applicable, adherence to plan policies and procedures, and claims editing logic.

Providers who are non-radiologists and who provide imaging services within an office setting must be privileged. Services for which a provider is privileged are considered integral to the practice of the provider, and are reimburseable. In most instances, privileging to perform specialty appropriate procedures is granted based on a provider's specialty designation.

Tufts Health Plan does not reimburse MRI/MRA, CT/CTA, and PET services performed by a non-radiologist. This includes both the technical and professional component. MRI/MRA, CT/CTA, and PET procedures must be performed in a contracted designated free-standing imaging center or a contracted hospital.

Refer to the Tufts Health Plan Speciality-Specific Privileging Tables (below) which list approved procedures by speciality and CPT code. Privileges based on service-specific training are also listed by CPT code. Physicians who do not have a speciality or service-specific training addressed in these tables do not have imaging privileges, and will not be reimbursed for any imaging services performed in their office setting. Physicians may not bill the Member for such services unless the Member has agreed in advance, in writing, to forego services by a privileged provider. In these cases, physicians are expected to direct patients back to their primary care physician (PCP) to have the necessary diagnostic imaging study performed by the appropriate Tufts Health Plan participating radiologist or imaging facility.

The following is additional information about the Tufts Health Plan Imaging Privileging Program:

- Mammography can be performed in the office setting regardless of physician specialty. All facilities must comply with the Mammography Quality Standards Act (MQSA) regulations. American College of Radiology (ACR) is required.
- Echocardiography requires no specific privileging.

- Mobile imaging services are subject to the same privileging restrictions established for the provider for whom they perform services, except for obstetrical (OB) ultrasound. If a mobile provider performs an OB ultrasound in an office setting, a Tufts Health Plan board-certified radiologist or American Institute of Ultrasound Medicine (AIUM) accredited physician must interpret the films.

Tufts Health Plan Specialty-Specific Privileging Tables

Board-certified or board-eligible physicians in the specialties indicated in the following tables can only be reimbursed for the imaging procedures listed under that specialty. A Tufts Health Plan radiologist or imaging provider must perform all other imaging procedures. The description under each speciality indicates whether the physician will be privileged for reimbursement of the technical or global component of each procedure.

NOTE Specialists who are privileged for the technical component only must have a Tufts Health Plan network radiologist perform the final reading (professional component) of the study. Specialists who are privileged to perform the global component are required to comply with the ACR standards for communication and to generate a written report.

The specialty-specific tables address the privileges for the following specialties:

- Anesthesiology or Physical Medicine and Rehabilitation
- Cardiovascular Disease
- Endocrinology
- General Vascular Surgery
- Hand Surgery
- Ophthalmology
- Orthopedic Surgery, Rheumatology
- Podiatric Medicine
- Primary Care Physicians (Internal Medicine, Family Practice, Pediatrics)
- Pulmonary Disease
- Urology

Anesthesiology or Physical Medicine and Rehabilitation

Providers who specialize in anesthesiology or physical medicine and rehabilitation are privileged to perform the following services and are eligible for global reimbursement, if appropriate.

TABLE 2. **Anesthesiology or Physical Medicine and Rehabilitation Services**

Procedure Code	Description
72275	Epidurography, radiological supervision and interpretation
76003	Fluoroscopic guidance for needle placement
76005	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures, including neurolytic agent destruction

Cardiovascular Disease

NOTE The professional component of these procedures must be performed by a radiologist.

TABLE 3. Cardiovascular Disease Services

Procedure Code	Description
71010	Chest, 1VW, frontal
71020	Chest, 2VW
71021	Chest, 2VW w/apical lordot
71022	Chest, 2VW w/obliques
71030	Chest, 4+VW
71035	Chest, special views (LAT decubitus, Bucky studies)
93875	Complete bilaterally study, extracranial study
93880	Duplex scan, extracranial arteries, complete
93882	Duplex scan, extracranial arteries, limited (follow-up)
93886	Doppler, intracranial arteries, complete
93888	Doppler, intracranial arteries, limited (follow-up)
93922	Physiologic extremity study
93923	Physiologic extremity study
93924	Physiologic extremity study
93925	Lower extremity artery study, complete
93926	Lower extremity artery study, limited
93930	Upper extremity artery study, complete
93931	Upper extremity artery study, complete
93965	Extremity veins study
93970	Extremity veins study, complete
93971	Extremity veins study, limited
93975	Duplex scan of arterial inflow & venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study

TABLE 3. Cardiovascular Disease Services

Procedure Code	Description
93976	Limited study
93978	Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; complete study
93979	Unilateral or limited study
93980	Duplex scan of arterial inflow & venous outflow of penile vessels; complete study
93981	Follow-up limited study
93990	Duplex scan, hemodialysis access

Endocrinology[1]

Providers specializing in endocrinology are privileged to perform the following services and are eligible for global reimbursement, if appropriate.

Procedure Code	Description
76942	Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision, and interpretation

General Vascular Surgery

Providers with a specialty of general vascular surgery are privileged to perform the following services and are eligible for global reimbursement, if appropriate.

TABLE 4. General Vascular Surgery Services

Procedure Code	Description
93875	Complete bilateral study, extracranial study
93880	Duplex scan, extracranial arteries, complete
93882	Duplex scan, extracranial arteries, limited (follow-up)
93886	Doppler, intracranial arteries, complete
93888	Doppler, intracranial arteries, limited (follow-up)
93922	Physiologic extremity study
93923	Physiologic extremity study

1. Effective 10/1/05

TABLE 4. General Vascular Surgery Services

Procedure Code	Description
93924	Physiologic extremity study
93925	Lower extremity artery study, complete
93926	Lower extremity artery study, limited
93930	Upper extremity artery study, complete
93931	Upper extremity artery study, complete
93965	Extremity veins study
93970	Extremity veins study, complete
93971	Extremity veins study, limited
93975	Duplex scan of arterial inflow & venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study
93976	Limited study
93978	Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; complete study
93979	Unilateral or limited study
93980	Duplex scan of arterial inflow & venous outflow of penile vessels; complete study
93981	Follow-up limited study
93990	Duplex scan, hemodialysis access

Hand Surgery

Providers who specialize in hand surgery are privileged to perform the following services and are eligible for global reimbursement, if appropriate.

TABLE 5. Hand Surgery Services

Procedure Code	Description
73070	Radiology exam, elbow, anteroposterior and lateral views
73080	Radiology exam, elbow, anteroposterior and lateral views; complete, minimum of three views
73090	Radiologic examination forearm; two views

TABLE 5. Hand Surgery Services

Procedure Code	Description
73100	X-ray exam of wrist
73110	X-ray exam of wrist, complete
73120	X-ray exam of hand, 2VW
73130	X-ray exam of hand, 3+VW
73140	X-ray exam of finger(s), 2+VW

Ophthalmology

Providers who specialize in ophthalmology are privileged to perform the following services and are eligible for global reimbursement, if appropriate.

TABLE 6. Ophthalmology Services

Procedure Code	Description
76510	Ophthalmic ultrasound, diagnostic, B-scan and quantitative A-scan performed during same patient encounter
76511	Ophthalmic ultrasound, diagnostic, A-scan only
76512	Ophthalmic ultrasound, diagnostic, contact B-scan (w/ or w/o A-scan)
76513	Ophthalmic ultrasound, diagnostic, immersion (water bath) B-scan
76514	Opthalmic ultrasound, corneal pachymetry
76516	Ophthalmic biometry by ultrasound, A-scan
76519	Ophthalmic biometry by ultrasound, A-scan, w/ intraocular lens power calculation
76529	Echo exam of eye for foreign body

Orthopedic Surgery, Rheumatology

Providers who specialize in orthopedic surgery or rheumatology are privileged to perform the following services and are eligible for global reimbursement, if appropriate.

TABLE 7. Orthopedic Surgery and Rheumatology Services

Procedure Code	Description
71100	Ribs, unilateral; 2 views
71101	Ribs, posteroanterior chest minimum 3 views

TABLE 7. Orthopedic Surgery and Rheumatology Services

Procedure Code	Description
71110	Ribs, bilateral; 3 views
71111	Ribs, posteroanterior chest minimum 4 views
72010	Spine, complete survey
72020	Spine, 1VW, specific level
72040	Cervical spine, 2VW
72050	Cervical spine, 4+VW
72052	Cervical spine, w/ oblique & flexion
72069	Thoracolumbar spine, standing
72070	Thoracic spine, 2VW
72072	Thoracic spine, 2VW, w/ swim view
72074	Thoracic spine, 4+VW, w/ obliques
72080	Thoracolumbar spine, 2VW
72090	Scoliosis study, supine & erect
72100	Lumbosacral spine, AP & LAT
72110	Lumbosacral spine, complete w/ obliques
72114	Lumbosacral spine, complete, bending
72120	Lumbosacral spine, 4+VW, bending
72170	Pelvis, AP only
72190	Pelvis, 3+VW
72200	X-ray exam of sacroiliac joints
72202	X-ray exam of sacroiliac joints
72220	X-ray exam of tailbone, 2+VW
73000	Clavicle, complete
73010	Scapula, complete
73020	Shoulder, 1VW

TABLE 7. Orthopedic Surgery and Rheumatology Services

Procedure Code	Description
73030	Shoulder, complete, 2+VW
73050	Acromioclavicular joints, bilateral
73060	Humerus, 2+VW
73070	Elbow 2VW (AP & LAT)
73080	Elbow, complete, 3+VW
73090	Forearm 2VW (AP & LAT)
73092	Upper extremity, infant, 2+VW
73100	Wrist 2VW (AP & LAT)
73110	Wrist, complete, 3+VW
73120	Hand 2VW
73130	Hand 3+VW
73140	Finger(s), 2+VW
73500	Hip, unilateral 1VW
73510	Hip, unilateral 2+VW
73520	Hips, bilateral 2+VW w/ AP pelvis
73540	Pelvis & Hips, infant 2+VW
73550	Femur 2VW (AP & LAT)
73560	Knee 2VW (AP & LAT)
73562	Knee w/ obliques 3+VW
73564	Knee w/ obliques, tunnel, patellar, standing
73565	Knees, both, stand, AP
73590	Tibia and Fibula AP & LAT
73592	Lower extremity infant 2+VW
73600	Ankle, 2VW (AP & LAT)
73610	Ankle, complete, 3+VW

TABLE 7. Orthopedic Surgery and Rheumatology Services

Procedure Code	Description
73620	Foot, 2VW (AP & LAT)
73630	Foot, complete, 3+VW
73650	Heel, 2+VW
73660	Toe(s) 2+VW
76006	Stress views

Podiatric Medicine

Providers who specialize in podiatric medicine are privileged to perform the following services and are eligible for global reimbursement, if appropriate.

TABLE 8. Podiatric Medicine Services

Procedure Code	Description
73600	Ankle, 2VW (AP & LAT)
73610	Ankle, complete
73620	Foot, 2VW (AP & LAT)
73630	Foot, complete, 3+VW
73650	Heel, 2+VW
73660	Toe(s) 2+VW

Primary Care Physicians (Internal Medicine, Family Practice, Pediatrics)

Providers are able to perform the following services and are eligible for reimbursement of the technical component only, if appropriate.

TABLE 9. Primary Care Physician Services

Procedure Code	Description
71010	Chest, 1VW, frontal
71020	Chest, 2VW
73020	Shoulder, 1VW
73030	Shoulder, complete 2+VW

TABLE 9. Primary Care Physician Services

Procedure Code	Description
73050	Acromioclavicular joints, bilateral
73060	Humerus, 2+VW
73070	Elbow 2VW (AP & LAT)
73080	Elbow, complete, 3+VW
73090	Forearm 2VW (AP & LAT)
73092	Upper extremity, infant, 2+VW
73100	Wrist 2VW (AP & LAT)
73110	Wrist, complete, 3+VW
73120	Hand 2VW
73130	Hand 3+VW
73140	Finger(s), 2+VW
73550	Femur 2VW (AP & LAT)
73560	Knee 2VW (AP & LAT)
73562	Knee w/ obliques 3+VW
73564	Knee w/ obliques, tunnel, patellar, standing
73565	Knee, both, stand, AP
73590	Tibia and Fibula AP & LAT
73592	Lower extremity infant 2+VW
73600	Ankle, 2VW (AP & LAT)
73610	Ankle, complete, 3+VW
73620	Foot, 2VW (AP & LAT)
73630	Foot, complete 3+VW
73650	Heel, 2+VW
73660	Toe(s) 2+VW
74000	Radiological exam/abdomen, single anteroposterior view
74022	Complete acute abdomen series

Pulmonary Disease

Providers who specialize in pulmonary disease are privileged to perform the following services and are eligible for reimbursement of the technical component only, if appropriate.

TABLE 10. Pulmonary Disease Services

Procedure Code	Description
71010	Chest, 1VW, frontal
71020	Chest, 2VW
71021	Chest, 2VW w/ apical lordot
71022	Chest, 2VW w/ obliques
71030	Chest, 4+VW
71035	Chest, special views (LAT decubitus, Bucky studies)

Urology

Providers who specialize in urology are privileged to perform the following services and are eligible for global reimbursement, if appropriate.

TABLE 11. Urology Services

Procedure Code	Description
74455	Urethrocystography, voiding
76770	Echography, retroperitoneal B-scan, complete
76775	Echo exam, retroperitoneal, limited
76856	Echo exam of pelvis, complete
76857	Echo exam of pelvis, limited
76870	Echo exam of scrotum
76872	Echo exam of prostate
76942	Ultrasound guide for needle biopsy

Service-Specific Certification

Tufts Health Plan requires service-specific certification or accreditation for physicians to be reimbursed for the following imaging services. The certifications and accreditations are required from the organizations listed within the category of service identified and physicians will only be reimbursed when Tufts Health Plan receives a copy of the certification or accreditation.

NOTE Service-specific privileges are not granted retroactively.

The following service-specific privileges allow for global reimbursement (physicians are required to comply with the American College of Radiology (ACR) standards for communication and to generate a written report).

The service-specific certifications are:

- Bone Densitometry
- Breast Ultrasound
- Nuclear Cardiology
- Obstetrical Ultrasound
- Vascular Ultrasound

Bone Densitometry

International Society for Clinical Densitometry (ISCD) certification is required for physicians who wish to perform and/or interpret the bone densitometry studies listed below. To perform these services, you must send a copy of the ISCD Certification and a completed Bone Density Equipment Information Form (in the Forms section of our Web site) to the attention of Tufts Health Plan Imaging Privileging Committee, 705 Mount Auburn Street, Mail Stop 84, Watertown, MA 02472. Once privileging is complete, the services listed below will be reimbursed globally.

For information about the individual certification programs and course availability, contact ISCD at 860-586-7563 or access their Web site at www.iscd.org.

TABLE 12. Bone Densitometry Services

Procedure Code	Description
76070	Quantitative CT, axial
76071	Quantitative CT, peripheral
76075	DEXA (Dual energy x-ray absorptiometry) bone density study
76076	DEXA, peripheral, appendicular skeleton
76077	Vertebral fracture assessment
76078	Radiologic Absorptiometry, photodensitometry
76977	Quantitative Ultrasound
G0130	SEXA

Nuclear Cardiology

Specific training is required of physicians who wish to perform and/or interpret the nuclear scans listed below. See certification criteria on the next page. Send certification to the attention of Tufts Health Plan's Imaging Privileging Committee, 705 Mount Auburn Street, Mail Stop 84, Watertown, MA 02474. Once privileging is complete, the services listed below will be reimbursed globally.

TABLE 13. Nuclear Cardiology Services

Procedure Code	Description
78460	Nuclear scan of the heart muscle, single
78461	Nuclear scans of the heart muscle, multiple
78464	Tomographic, single study
78465	Tomographic, multiple study
78466	Myocardial imaging
78468	With ejection fraction by first pass
78469	Tomographic SPECT
78472	Nuclear scan, cardiac blood pool, single, gated equilibrium
78473	Multiple studies
78478	Nuclear scan of heart muscle with wall motion
78480	Nuclear scan of heart muscle with ejection fraction
78481	Nuclear scan, cardiac blood pool
78483	Nuclear scan, multiple studies
78494	Cardiac blood pool imaging, SPECT at rest
78496	Cardiac blood pool imaging, single study
78890	Automated data, Nuclear Med.
A4641	Supply of radiopharmaceutical diagnostic imaging agent, not otherwise classified

NOTE Effective for dates of service on or after April 1, 2006, Tufts Health Plan will transition from a prior consultation program to a prior authorization program for outpatient high-tech imaging services. This program will continue to be managed by a third-party vendor, National Imaging Associates. The above-listed cardiology codes require prior authorization for Tufts Health Plan Members in the following products: Health Maintenance Organization (HMO), Point of Service (POS), Exclusive Provider Option (EPO), Preferred Provider Organization (PPO), Navigator, and Liberty by Tufts Health Plan.

Prior authorization can be obtained by calling National Imaging Associates (866-642-9703) prior to scheduling the test. For additional information, refer to the Payment Policies or Prior Authorization section on our Web site.

Prior consultation can be obtained by calling National Imaging Associates at 866-642-9703 prior to the test being scheduled. Refer to the Prior Authorization section of our Web site for further information.

Criteria Permitting a Physician to Officially Perform/Interpret Nuclear Cardiology Studies

Certification requires meeting one of the following criteria:

- The cardiologist has completed one-year training in nuclear cardiology.
- The cardiologist is board-certified in Nuclear Medicine.
- Cardiologists who finish their cardiology training in July 1997 or later must satisfy Level 2 training in nuclear cardiology as specified by the official 1995 American College of Cardiology/American Society of Nuclear Cardiology (ACC/ASNC) Training Guidelines. They must also achieve board certification in cardiovascular diseases by the American Board of Internal Medicine within two years of completing their fellowship.
- Cardiologists currently in clinical practice, or who have completed their training prior to July 1987 must satisfy both of the following criteria:

  a. The physician must have board certification in cardiovascular diseases or board eligibility if the physician completed the fellowship less than two years ago.

  b. The physician must have participated in a formal course designed to train cardiologists to interpret nuclear cardiology studies. For recent fellows, this may have been part of their fellowship. For other cardiologists, the following criteria apply:

     i. 40 hours of formal training in cardiology nuclear imaging in a course accredited by the American College of Cardiology (ACC), American Society of Nuclear Cardiology, Society of Nuclear Medicine, American Board of Radiology, or American Board of Nuclear Medicine.

     ii. 20 hours of documented hands-on experience in nuclear cardiology at a teaching hospital.

The certification examination in nuclear cardiology is acceptable as an alternative to the above.

Individual exceptions are considered after review by the Clinical Services department.

Obstetrical Ultrasound

Accreditation by the American Institute of Ultrasound in Medicine (AIUM) is required for physicians who wish to perform and/or interpret the obstetrical and gynecological ultrasounds listed below. If physicians are providing these services to their patients through a mobile imaging service, a board-certified radiologist or AIUM-accredited physician must perform the interpretation. To contact AIUM for more information on becoming an accredited facility, call 1-800-638-5352 or visit their Web site at www.aium.org. Once complete, the accreditation must be sent to the attention of the Tufts Health Plan Imaging Privileging Committee, 705 Mt. Auburn Street, Mailstop 84, Watertown, MA 02472. Once privileging is complete, the services listed below will be reimbursed globally.

TABLE 14. Obstetrical Ultrasound Services

Procedure Code	Description
76801	OB Ultrasound, pregnant uterus, <14 weeks, single fetus
76802	Each additional gestation, <14 weeks
76805	OB US, complete
76810	OB US, complete multi gestate
76811	OB Ultrasound, detailed fetal anatomic exam, single fetus
76812	OB Ultrasound, detailed fetal anatomic exam, each additional fetus
76815	OB US, limited
76816	OB US, follow-up (repeat)
76817	Ultrasound, pregnant uterus, real time with image documentation, transvagina
76818	Fetal biophysical profile
76819	Fetal biophysical profile; without non-stress testing
76820	Doppler velocimetry, fetal; umbilical artery
76821	Doppler velocimetry, fetal; middle cerebral artery
76825	Fetal Echocardiography, real time with image documentation (2D) with or without M-mode recording
76826	Fetal Echocardiography, follow-up (repeat)
76827	Fetal Doppler Echocardiography
76828	Fetal Doppler Echocardiography, follow-up (repeat)
76830	Transvaginal ultrasound
76831	Hysterosonography, with or without color flow doppler
76856	Echography, pelvic B-scan/complete
76857	Echography, pelvic B-scan/limited
76941	Ultrasound guide for intrauterine fetal transfusion
76945	Ultrasound guide for Chorionic Villus sampling

TABLE 14. Obstetrical Ultrasound Services

Procedure Code	Description
76946	Ultrasound guide for amniocentesis and amnio guidance codes
76948	Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation

Breast Ultrasound

Accreditation by the American Institute of Ultrasound in Medicine (AIUM) or certification by the American Society of Breast Surgeons (ASBS) is required for all physicians who wish to perform and/or interpret the breast ultrasounds listed below. A copy of the accreditation/certification must be sent to the attention of the Tufts Health Plan Imaging Privileging Committee, 705 Mount Auburn Street, Mailstop 84, Watertown, MA 02472. **Initial privileging with an ASBS certification must be reprivileged (at the expiration of the ASBS certification) with an AIUM accreditation.** Once privileging is complete, the services listed below will be reimbursed globally.

To contact AIUM for more information on becoming an accredited facility, call 1-800-638-5352 or visit www.aium.org.

Procedure Code	Description
76645	Ultrasound breasts (unilateral or bilateral), B-scan and/or real time with imaging documentation
76942	Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation

Vascular Ultrasound

Accreditation by the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL) is required for physicians who are not board certified or eligible in general vascular surgery or cardiovascular disease. For more information about this accreditation, contact ICAVL at 401-872-0100 or access their Web site at www.icavl.org. A copy of the accreditation must be sent to the attention of the Tufts Health Plan Imaging Privileging Committee, 705 Mount Auburn Street, Mail Stop 84, Watertown, MA 02472. Once privileging is complete, the services listed below will be reimbursed globally.

TABLE 15. Vascular Ultrasound Services

Procedure Code	Description
93875	Complete bilateral study, extracranial study
93880	Duplex scan, extracranial arteries, complete
93882	Duplex scan, extracranial arteries, limited (follow-up)
93886	Doppler, intracranial arteries, complete

TABLE 15. Vascular Ultrasound Services

Procedure Code	Description
93888	Doppler, intracranial arteries, limited (follow-up)
93922	Physiologic extremity study
93923	Physiologic extremity study
93924	Physiologic extremity study
93925	Lower extremity artery study, complete
93926	Lower extremity artery study, limited
93930	Upper extremity artery study, complete
93931	Upper extremity artery study, complete
93965	Extremity veins study
93970	Extremity veins study, complete
93971	Extremity veins study, limited
93975	Duplex scan of arterial inflow & venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study
93976	Limited study
93978	Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; complete study
93979	Unilateral or limited study
93980	Duplex scan of arterial inflow & venous outflow of penile vessels; complete study
93981	Follow-up limited study
93990	Duplex scan, hemodialysis access